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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE INTUITIVE SURGICAL SHAREHOLDER DERIVATIVE LITIGATION	Lead Case No. 5-14-CV-00515-EJD
This Document Relates To: ALL ACTIONS.	VERIFIED CONSOLIDATED SHAREHOLDER DERIVATIVE COMPLAINT DEMAND FOR JURY TRIAL

REDACTED VERSION OF VERIFIED CONSOLIDATED SHAREHOLDER DERIVATIVE COMPLAINT SOUGHT TO BE SEALED

1. Lead Plaintiff Robert Berg ("Plaintiff"), by and through his undersigned attorneys, hereby submits this Verified Consolidated Shareholder Derivative Complaint (the "Complaint") for the benefit of Nominal Defendant Intuitive Surgical, Inc. ("Intuitive" or the "Company") against certain members of its Board of Directors (the "Board") and executive officers seeking to remedy Defendants' breaches of fiduciary duties and unjust enrichment from 2011 to the present (the "Relevant Period").The allegations in this Complaint are made upon Plaintiff's personal knowledge with regard to Plaintiff's own acts and upon information and belief as to all other matters.

2. Plaintiff's information and belief is based upon, among other things, the investigation conducted by Lead Counsel in the above-captioned shareholder derivative action (the "Action"), the Weiser Law Firm, P.C. ("Lead Counsel"), and other counsel that Lead Counsel has associated with for purposes of this Action.[1] This investigation included, among other things, the review of: (i) [redacted] produced by Intuitive in response to a March 25, 2014 inspection demand made pursuant to § 220 of the Delaware General Corporation Law, 8 *Del. C.* § 220 (the "Demand Letter");[2] (ii) materials created by the Food and Drug Administration (the "FDA") in connection with its regulatory oversight of Intuitive; (iii) Company filings with the U.S. Securities and Exchange Commission (the "SEC"); (iv) court records; (v) Company press releases and earnings conference call transcripts; and (vi) scholarly studies, news articles, analyst reports, and other publicly available information.

3. This case arises from Defendants' repeated violation of their fiduciary duties and serious misconduct, including: (a) knowingly failing to comply with FDA regulations when

[1] Following the entry of this Court's July 30, 2014 Order appointing Lead Counsel in this Action, Lead Counsel communicated with the law firms of Grant & Eisenhofer P.A. ("G&E") and Bernstein Litowitz Berger & Grossmann LLP ("BLBG"), which have been appointed to serve as co-lead counsel in a substantially similar shareholder derivative action brought on behalf of Intuitive in the Delaware Court of Chancery, captioned *City of Plantation Public Officers' Employees' Retirement System v. Guthart, et al.*, C.A. No. 9726-CB (the "Delaware Action"). As a result of those communications, in the interests of efficiency and judicial economy, Lead Counsel, G&E, and BLBG agreed to cooperate with one another and coordinate their efforts, and that this Action on the Company's behalf would proceed while the Delaware Action will be stayed.

[2] The Demand Letter was issued on behalf of the plaintiff to the Delaware Action by its counsel, G&E and BLBG.

responding to severe and hazardous defects in the Company's flagship product, the da Vinci surgical systems ("*da Vinci*"); (b) knowingly failing to establish sufficient internal controls to ensure compliance with FDA regulations; and (c) selling over $219 million worth of their personally-held Intuitive shares at artificially high prices based on their possession of material, adverse, non-public information. Significantly, as alleged herein, a majority of the members of the Board at the time this Action was initiated were among the Defendants who executed these illicit insider sales.

4. Intuitive designs, manufactures, and markets *da Vinci*, and related instruments and accessories. Intuitive's *da Vinci* surgical system translates a surgeon's natural hand movements, which are performed on instrument controls at a console, into corresponding micro-movements of instruments positioned inside the patient through small incisions or ports.

5. Using the *da Vinci* system, surgeons can perform operations remotely using tiny instruments attached to robot arms that are threaded into a patient's body through small incisions. Both before and throughout the Relevant Period, all or virtually all of Intuitive's revenues were (and still are) derived from: (i) selling the *da Vinci* system platform itself; (ii) selling component parts (such as the tiny instruments) to existing *da Vinci* system owners, allowing for greater volume and breadth of procedures performed; and (iii) servicing previously sold *da Vinci* systems. Intuitive generated almost $1.8 billion in revenues in 2011, almost $2.2 billion in revenues in 2012, and almost $2.3 billion in revenues in 2013, all or almost all related to the *da Vinci* system. As further alleged herein, when serious health and safety issues with the *da Vinci* system and attendant FDA scrutiny came to light in the second fiscal quarter of 2013, it resulted in a significant decline in the Company's revenues for the third fiscal quarter of 2013.

6. As alleged with particularity herein, over the last several years, Defendants, including all of the members of the Board, became aware of a rising tide of health and safety problems caused by the *da Vinci* system, which have resulted in hundreds of serious injuries and dozens of fatalities since 2011. Yet, Defendants kept these problems a secret for as long as they could, in violation of their fiduciary duties of loyalty and good faith.

7. Certain of the instruments used by the *da Vinci* system carry an electrical charge and are used, for example, to cauterize tissue. The charged portions of the instruments are supposed to

be insulated with a device referred to as the "Tip Cover." The Tip Cover is a silicon and plastic sheath that is intended to prevent electricity from escaping the intended area. However, due to a design flaw in the *da Vinci* system, the Tip Covers can fail to stand up to the wear and tear of use. Specifically, surgeons inadvertently crack the Tip Covers during procedures when they clean instruments by scraping one against another. If a Tip Cover is compromised, electricity often "arcs" from the instrument into the patient's body. This "arcing" can cause very dangerous burns and puncture internal organs. This condition is particularly dangerous because surgeons often are unaware of the problem, given the limitations on their field of view via the console.

8. During the Relevant Period, before it came to light publicly, Intuitive's senior management team and the entire Board were aware of this defect. Pursuant to applicable FDA reporting regulations, in every instance in which a hospital or surgeon encountered an adverse event involving the *da Vinci* system that resulted in a fatality or serious injury (including those related to the Tip Cover malfunction), the user was required to report the adverse event to the manufacturer, Intuitive. Intuitive received dozens of reports regarding the *da Vinci* arcing problem during the Relevant Period.

9. Intuitive, in turn, was required by regulation to report all such adverse events to the FDA. It failed, however, to do so. In late 2012, the FDA launched a thorough and lengthy investigation into Intuitive's FDA reporting practices. During the course of that investigation, Intuitive was forced to admit publicly that the Company regularly downgraded "serious injury" reports to "other" in an apparent effort to avoid FDA scrutiny, and failed to make other reports altogether.

10. Given how dependent the Company's revenues were at all times on the *da Vinci* system, Defendants (including the Board) were highly motivated to keep the *da Vinci* system's health and safety concerns "under wraps." Instead of reporting the Tip Cover problem to the FDA and issuing any public disclosures regarding it, Intuitive launched a "secret recall" campaign in an attempt to deal with the issue without having to face government monitoring or public scrutiny.

11. For example, in October 2011, under Defendants' direction and on their watch, Intuitive sent letters directly to hospitals and surgeons providing advice on how to avoid arcing.

Defendants' failure to report this secret recall was a serious violation of FDA regulations, and was particularly egregious given that in 2002 and again in 2008, the FDA had issued warnings to the Company for failing to adequately report corrective actions.

12. Specifically, in October 2011, Intuitive, under Defendants' direction and on their watch, sent letters directly to hospitals and surgeons informing them that, despite prior representations to the contrary, the *da Vinci* system was ***not*** approved for thyroidectomies. Marketing a medical device for "off-label" uses is yet another serious violation of FDA regulation. And again, this was a violation that the FDA had previously found at Intuitive in 2001. Significantly, the FDA found in 2013 that these covert recall letters were sent in response to adverse event complaints lodged by users of the *da Vinci* system with Intuitive.

13. Given Intuitive's persistent and multi-layered violations of FDA regulations, it is abundantly clear that, among other things, Defendants breached their fiduciary duties by failing to ensure that Intuitive had in place a system of adequate internal controls for reporting adverse events and corrective actions to the FDA. [redacted]

14. Intuitive's concealment of *da Vinci* system health and safety concerns was not limited to violations of the Company's FDA reporting obligations. As part of Defendants' effort to sweep all safety concerns about *da Vinci* under the rug, or at least to keep them hidden for as long as they possibly could, Defendants regularly caused Intuitive to issue materially false and misleading misstatements in SEC filings touting the purported safety of the *da Vinci* system and the status of the Company's regulatory compliance. The disclosures the Company did make simply demonstrate that the Defendants understood what was required for compliance, but failed to execute. Based on Intuitive's public statements, the Company's stock price skyrocketed during the Relevant Period, reaching an all-time high of nearly $595 per share in mid-April 2012.

15. Similarly, under Defendants' direction, the Company's insurance carriers were lied to. When Intuitive realized that it was facing hundreds or potentially thousands of products liability

lawsuits, it entered into tolling agreements with potential claimants. While these claims were tolled, Intuitive – under Defendants' direction – executed new products liability insurance policies with two separate insurance carriers, Illinois Union Insurance Co. ("IUIC") and Navigators Specialty Insurance Company ("NSIC"). Those insurance carriers have now brought actions against Intuitive to invalidate the policies on the grounds that Intuitive misrepresented its exposure to potential lawsuits by failing to disclose that it had entered into tolling agreements for numerous claims. Thus, Intuitive may be responsible for all pending, threatened, or contemplated products liability lawsuits due to this scheme to renew the Company's insurance while hiding its potentially enormous products liability exposure.

16. Defendants' long-running scheme began to unravel in September 2012, although the serious risks posed by the *da Vinci* system would not become known publicly until early 2013. Specifically, in September 2012, in the wake of reports in the surgical community regarding the health and safety implications of the *da Vinci* system, top Intuitive officials met informally with FDA officials. The FDA warned against misclassifying adverse events for reporting purposes. Defendants did not publicly disclose that this meeting with the FDA even occurred, much less the substance of the meeting.

17. Within months, the FDA determined that the September 2012 meeting was not, without more, going to resolve Intuitive's regulatory issues, including the disclosure of the true number of injuries and deaths caused by the *da Vinci* system. Thus, in January 2013, the FDA initiated a safety probe into the *da Vinci* system.

18. On February 28, 2013, *Bloomberg* broke the story of the FDA's ongoing investigation into Intuitive. On that news, Intuitive's stock price immediately fell by nearly $64 per share – over 11% – from $573.52 to $509.89.

19. On March 5, 2013, *Bloomberg* published another detailed article regarding Intuitive, which described the serious health risks associated with the *da Vinci* system and the swelling number of resultant lawsuits. For example, *Bloomberg* reported that "[r]obot systems made by Intuitive . . . are linked to at least 70 deaths . . . since 2009" and that "tough new questions about safety raised in lawsuits and in adverse incident reports to U.S. regulators may threaten the company's growth."

20. On March 13, 2013, Intuitive was forced to issue a statement commenting on the negative press coverage regarding the safety of the *da Vinci* system (or lack thereof) and Intuitive's "medical device reporting practices." Therein, Intuitive admitted that the Company's adverse event reporting practices had been deficient.

21. On March 15, 2013, *Bloomberg* reported that according to the American Congress of Obstetricians and Gynecologists ("ACOG"), "expertise with Intuitive's da Vinci robot system is limited and surgeons learning the new technology may have higher rates of complications."

22. Between February 27, 2013 and March 15, 2013, as more and more news sources picked up on the serious regulatory issues at Intuitive, the Company's stock price fell by nearly 20%, from $573.52 per share to $459.44 per share.

23. On July 16, 2013, the FDA issued a warning letter to the Company ("the July 16, 2013 Warning Letter") for violating applicable FDA rules and regulations. FDA warning letters are understood to be the final FDA actions taken before the initiation of proceedings that could result in civil penalties or disapproval of a regulated product. In response to Defendants' disclosure of the Company's receipt of the July 16, 2013 Warning Letter, made on July 18, 2013, the Company's stock price dipped below $400 per share for the first time in almost two years.

24. Throughout the Relevant Period, Defendants were aware of the material, nonpublic information regarding, *inter alia*, serious health and safety concerns with the *da Vinci* system and Intuitive's FDA reporting violations. Nevertheless, top Company insiders, including a majority of the members of the Board at the time this Action was initiated, perpetrated a massive insider stock selling scheme. Collectively, these Defendants sold over 411,000 shares of Intuitive stock at artificially high prices for over $219 million in proceeds during the Relevant Period.

25. Notably, these insider sales were often executed at the same time that, per the Board's authorization, the Company was buying back hundreds of millions of dollars' worth of its own stock with Company (*i.e.*, shareholders') money, propping up Intuitive's share price even further. Specifically, in February 2011, the Board increased its authorization of a stock repurchase of up to

$400 million,[3] and in October 2011 – the same time Defendants' "secret recall" campaign began – the Board increased its authorization for stock repurchases by another $500 million. Later, in March 2013, the Board authorized another $1 billion in stock repurchases.

26. As a result of Defendants' breaches of fiduciary duty and other serious misconduct, the Company has been seriously harmed. Among other things, based on its most recent public disclosures, the Company currently faces at least 95 different products liability lawsuits (with many others tolled), exposing the Company to potentially massive civil liability. Indeed, per the Company's Quarterly Report on Form 10-Q for the second fiscal quarter of 2014, filed with the SEC on July 24, 2014, the Company has been forced to take a $77 million pre-tax charge to reflect estimated costs of resolving "a number of product liability claims," explaining that "[t]o date, approximately 4,400 claims have been added to the tolling agreements and/or submitted to the mediation program."

27. Due to Defendants' misconduct in withholding information about products liability lawsuits from Intuitive's insurance carriers, Intuitive's potentially massive liability may not be covered, in whole or in part, by valid insurance policies, and thus may need to be paid out directly by the Company. On October 21, 2013, IUIC sued Intuitive in the U.S. District Court for the Northern District of California seeking to rescind Intuitive's products liability insurance coverage due to misrepresentations in the number of products liability claims Intuitive was facing. On December 16, 2013, NSIC also sued Intuitive in a substantially similar lawsuit. In answering the complaints filed by IUIC and NSIC, the Company has admitted that it did not publicly disclose the tolling agreements until April 19, 2013 despite the fact that Intuitive "knew its counsel had been entering into tolling agreements in January and February 2013."

28. Putting aside the prospect of potentially massive civil liability for the Company, Defendants' misconduct has also resulted in heightened regulatory scrutiny of Intuitive, including (as discussed herein) the FDA's issuance of the July 16, 2013 Warning Letter.

[3] In July 2010, the Board had authorized the repurchase of up to $150 million worth of Company stock.

29. Finally, Defendants' misconduct has seriously harmed the Company's reputation and damaged the goodwill it had previously cultivated with the medical community, commentators, the press, and the public, resulting in an attendant decline in stock price, revenue, and sales. For example, in the second quarter of 2013 – the quarter before Intuitive's secret safety recalls and regulatory problems became public – Intuitive generated approximately $578.5 million in revenues. In the very next quarter, Intuitive's revenues dropped to $499 million – a decline of almost 14%.

30. Defendants' violations of their fiduciary duties of loyalty and good faith and other misconduct has severely damaged the Company, and they should be held accountable.

JURISDICTION AND VENUE

31. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a)(2) in that Plaintiff and Defendants are citizens of different states and/or countries and the matter in controversy exceeds $75,000.00, exclusive of interests and costs. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. §1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

32. Venue is proper in this district because a substantial portion of the transactions and wrongs complained of herein, including Defendants' primary participation in the wrongful acts detailed herein, occurred in this district. One or more of the Defendants either resides in or maintains executive offices in this district, and Defendants have received substantial compensation in this district by engaging in numerous activities and conducting business here, which had an effect in this district.

THE PARTIES

33. Plaintiff is a current shareholder of Intuitive and has been continuously since January 2009. Plaintiff is a citizen of Wisconsin.

34. Nominal party Intuitive is a Delaware corporation with its executive offices located at 1266 Kifer Road, Building 101, Sunnyvale, California 94086. According to its public filings, the Company designs, manufactures, and markets *da Vinci* surgical systems, and related instruments and accessories, EndoWrist instruments consisting of forceps, scissors, electrocautery, scalpels, and other surgical tools, and EndoWrist Stapler 45 instrument, a wristed stapling instrument intended for

resection, transaction, and/or creation of, such as sterile drapes, 3-D stereo endoscopes, camera heads, light guides, and other items that are used in conjunction with the da Vinci surgical system.

35. Defendant Gary S. Guthart ("Guthart") has served as the Company's Chief Executive Officer ("CEO") since January 2010 and as the Company's President since 2007. Prior to that, Guthart had served as the Company's Chief Operating Officer ("COO") since February 2006. In addition, Defendant Guthart has served as a director of the Company since 2009. Defendant Guthart joined the Company in 1996. During the Relevant Period, Guthart sold 17,000 Intuitive shares at artificially inflated stock prices for proceeds of approximately $8.7 million. Upon information and belief, Defendant Guthart is a citizen of California.

36. Defendant Marshall L. Mohr ("Mohr") has served as the Company's Senior Vice President and Chief Financial Officer ("CFO") since March 2006. During the Relevant Period, Mohr sold 26,800 Intuitive shares at artificially inflated stock prices for approximately $15 million in proceeds. Upon information and belief, Defendant Mohr is a citizen of California.

37. Defendant Lonnie M. Smith ("Smith") served as the Company's CEO from June 1997 to January 2010. From January 2010 until at least 2013, Defendant Smith continued to serve as an executive of the Company. In addition, Defendant Smith has served as Chairman of the Board since 1997. During the Relevant Period, Smith sold 187,422 Intuitive shares at artificially inflated stock prices for approximately $100 million in proceeds. Upon information and belief, Defendant Smith is a citizen of California.

38. Defendant David J. Rosa ("Rosa") has served as the Company's Executive Vice President and Chief Scientific Officer since 2014. In addition, Defendant Rosa previously served as the Company's Senior Vice President, Scientific Affairs. According to the Company's public filings, Rosa has held "leadership positions" in engineering, clinical development, marketing and product development since joining the Company in 1996. During the Relevant Period, Rosa sold 11,000 Intuitive shares at artificially inflated stock prices for approximately $5.7 million in proceeds. Upon information and belief, Defendant Rosa is a citizen of California.

39. Defendant Mark J. Meltzer ("Meltzer") has served as the Company's Senior Vice President, General Counsel and Chief Compliance Officer since 2007. During the Relevant Period,

Meltzer sold 27,500 Intuitive shares at artificially inflated stock prices for approximately $15.2 million in proceeds. Upon information and belief, Defendant Meltzer is a citizen of California.

40. Defendant Jerome J. McNamara ("McNamara") has served as the Company's Executive Vice President, Worldwide Sales and Marketing since 2007. During the Relevant Period, McNamara sold 55,625 Intuitive shares at artificially inflated stock prices for approximately $31.5 million in proceeds. Upon information and belief, Defendant McNamara is a citizen of California.

41. Defendant Augusto V. Castello ("Castello") has served as the Company's Senior Vice President, Product Operations since 2007. During the Relevant Period, Castello sold 26,250 Intuitive shares at artificially inflated stock prices for approximately $15.1 million in proceeds. Upon information and belief, Defendant Castello is a citizen of California.

42. Defendant Salvatore J. Brogna ("Brogna") has served as the Company's Senior Vice President, Product Development since 2010. Previously, Defendant Brogna served as the Company's Vice President, Engineering from 2005 until 2010, and as the Company's Director, Mechanical Engineering from 1999 until 2005. During the Relevant Period, Brogna sold 39,042 Intuitive shares at artificially inflated stock prices for approximately $18.3 million in proceeds. Upon information and belief, Defendant Brogna is a citizen of California.

43. Defendant Colin Morales ("Morales") has served as the Company's Senior Vice President, Manufacturing and Service Operations since 2010. Morales previously served as the Company's Vice President of the Customer Support Group from July 2005 until 2010, and as Director of Field Service from 1999 until 2005. During the Relevant Period, Morales sold 4,760 Intuitive shares at artificially inflated stock prices for approximately $2.3 million in proceeds. Upon information and belief, Defendant Morales is a citizen of California.

44. Defendant Craig H. Barratt ("Barratt") has served as a director of the Company since April 2011. Upon information and belief, Defendant Barratt is a citizen of California.

45. Defendant Eric H. Halvorson ("Halvorson") has served as a director of the Company since June 2003. In addition, Defendant Halvorson has served as a member of the Board's Audit Committee (the "Audit Committee") since 2003. Further, Defendant Halvorson served as a member of the Board's Compensation Committee (the "Compensation Committee") since 2010. During the

Relevant Period, Halvorson sold 4,500 Intuitive shares at artificially inflated stock prices for proceeds of approximately $2.5 million. Upon information and belief, Defendant Halvorson is a citizen of California.

46. Defendant Amal M. Johnson ("Johnson") has served as a director of the Company since April 2010. In addition, Defendant Johnson served as a member of the Compensation Committee since 2010. Upon information and belief, Defendant Johnson is a citizen of California.

47. Defendant Alan J. Levy ("Levy") has served as a director of the Company since 2000. In addition, Defendant Levy served as a member of the Compensation Committee since 2000. During the Relevant Period, Levy sold 6,750 Intuitive shares at artificially inflated stock prices for approximately $3.4 million in proceeds. Upon information and belief, Defendant Levy is a citizen of California.

48. Defendant Floyd D. Loop ("Loop") has served as a director of the Company since 2005. During the Relevant Period, Loop sold 5,000 Intuitive shares at artificially inflated stock prices for approximately $2 million in proceeds. Upon information and belief, Defendant Loop is a citizen of Ohio.

49. Defendant Mark J. Rubash ("Rubash") has served as a director of the Company since October 2007. In addition, Defendant Rubash served as the Chairman of the Audit Committee since 2007. Upon information and belief, Defendant Rubash is a citizen of California.

50. Defendant George Stalk Jr. ("Stalk") has served as a director of the Company since 2007. In addition, Defendant Stalk served as a member of the Audit Committee since 2009. Upon information and belief, Defendant Stalk is a citizen of Canada.

51. Collectively, Defendants Guthart, Mohr, Smith, Rosa, Meltzer, McNamara, Castello, Brogna, Morales, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk shall be collectively referred to herein as the "Defendants."

52. Collectively, Defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk are referred to herein as the "Director Defendants."

53. Collectively, Defendants Guthart, Smith, Mohr, Brogna, Castello, McNamara, Metzler, Morales, and Rosa are referred to herein as the "Officer Defendants."

54. Collectively, Defendants Halvorson, Rubash, and Stalk shall be collectively referred to herein as the "Audit Committee Defendants."

55. Collectively, Defendants Halvorson, Johnson, and Levy are referred to herein as the "Compensation Committee Defendants."

56. Collectively, Defendants Smith, Guthart, Mohr, Rosa, Meltzer, McNamara, Castello, Brogna, Loop, Morales, Halvorson and Levy shall be collectively referred to herein as the "Insider Selling Defendants."

DEFENDANTS' DUTIES

57. By reason of their positions as officers, directors, and/or fiduciaries of Intuitive and because of their ability to control the business and corporate affairs of Intuitive, Defendants owed Intuitive and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Intuitive in a fair, just, honest, and equitable manner. Defendants were and are required to act in furtherance of the best interests of Intuitive and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to Intuitive and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

58. Defendants, because of their positions of control and authority as directors and/or officers of Intuitive, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Intuitive, each of the Defendants had knowledge of material non-public information regarding the Company.

59. To discharge their duties, the officers and directors of Intuitive were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Intuitive were required to, among other things:

(a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

(b) Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and

(c) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

60. The Company's Code of Business Conduct and Ethics (the "Code") applies to all directors, officers and employees of Intuitive, and therefore applies to all of the Defendants. The Code sets forth the following, in relevant part:

> Employees who possess or have access to material, non-public information gained through their work at ISI may not use that information to trade in ISI securities or the securities of another company to which the information pertains. Further, employees may not engage in any other action to take advantage of, or pass on to others (*i.e.*, "tip"), material information before its release to the public at large until three days after that information has been publicly disclosed. These restrictions also apply to your family members, friends, or associates, and are in addition to your obligations with respect to nonpublic information generally, as discussed above.
>
> Material nonpublic information includes any information that is not known to the general public and that a reasonable investor would consider important in a decision to buy, hold, or sell securities. Examples of such information include earnings or other financial results, new or lost contracts or products, sales results (including system sales and procedure volumes), important personnel changes, business plans, possible mergers, acquisitions, or joint ventures, important litigation developments, and important regulatory, judicial or legislative actions.
>
> Employees who possess or have access to material inside information relating to quarterly or annual financial results are prohibited from trading in ISI securities during certain "blackout" periods. Additional restrictions on trading or speculating in ISI stock apply to certain officers and selected employees as determined by the CFO.
>
> The law and Company policy do permit employees to trade in ISI securities regardless of their awareness of material nonpublic information if the transaction is made pursuant to a pre-arranged trading plan that was established in compliance with applicable law and was entered into when the person was not in possession of material nonpublic information.

61. Pursuant to the Compensation Committee's charter, the members of the Compensation Committee are specifically charged with "[r]eview[ing] and approv[ing] all compensation programs applicable to the executive officers . . . [;] [a]pprov[ing] any new compensation plan or any material change to an existing compensation plan . . . [;] oversee[ing] the activities of the individuals and committees responsible for overseeing the Company's compensation plans, and discharg[ing] any responsibilities imposed on the Committee by any of those plans . . . [;] oversee[ing] regulatory compliance with respect to compensation matters . . . [;] [addressing] [a]ny other compensation matters as from time to time may be directed by the Board . . . [;] [r]eviewing and recommend[ing] the level of compensation for the Company's Board . . . [and ;] [r]eview[ing] . . . whether the Company's compensation-related policies and practices . . . encourage unnecessary or excessive risk taking."

62. Pursuant to the Audit Committee's Charter, the members of the Audit Committee are required, *inter alia*, to:

(a) Oversee the integrity of the Company's financial statements, accounting and financial reporting processes and financial statement audits;

(b) Oversee the Company's compliance with legal and regulatory requirements related to financial reporting;

(c) Meet with management and the independent auditor to review and discuss the Company's annual financial statements and quarterly financial statements (prior to the Company's Form 10-K or 10-Q filings or release of earnings), as well as all internal control reports (or summaries thereof);

(d) Review other relevant reports or financial information submitted by the Company to any governmental body or the public, including Form 10-K, Form 10-Q, proxy statements, management certifications as required by the Sarbanes-Oxley Act of 2002 ("SOX Certifications"), and relevant reports rendered by the independent auditor (or summaries thereof);

(e) Recommend to the Board whether the financial statements should be included in the annual report on Form 10-K;

(f) Discuss earnings press releases, including the type and presentation of information, paying particular attention to any pro forma or adjusted non-GAAP information;

(g) Discuss financial information and earnings guidance provided to analysts and ratings agencies;

(h) Review the integrity of the Company's financial reporting processes (both internal and external), and the internal control structure (including disclosure controls and procedures and internal control over financial reporting);

(i) Review major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles; major issues as to the adequacy of the Company's internal controls; and any special audit steps adopted in light of material control deficiencies;

(j) Review any material reports or inquiries received from regulators, governmental agencies or employees that raise material issues regarding the Company's financial statements and accounting or compliance policies; and

(k) Discuss policies with respect to risk assessment and risk management, including appropriate guidelines and policies to govern the process, as well as the Company's major financial risk exposures and the steps management has undertaken to control them.

SUBSTANTIVE ALLEGATIONS

A. Background of the Company

63. Intuitive was founded in 1995 to adapt a prototype robotic surgery platform developed for the U.S. Army to commercial use. In January 1999, Intuitive launched the "*da Vinci* system." The *da Vinci* system consists of a console with "video game style" controls and a live video stream from inside a patient's body, a patient-side cart from which the *da Vinci* System's robotic arms manipulate surgical instruments that are branded "EndoWrist," and the EndoWrist instruments themselves.

64. The EndoWrist instruments are a set of surgical tools (*i.e.*, scalpels, scissors, forceps, and retractors) designed for specific surgical tasks, such as cutting, clamping, suturing, or

cauterizing. The *da Vinci* system is designed to allow surgeons to make small incisions, and then perform surgery inside the patient's body using the EndoWrist instruments.

65. The *da Vinci* system is Intuitive's only product. All or virtually all of Intuitive's revenues are derived from: (i) selling the *da Vinci* system platform itself, (ii) selling component parts (such as the EndoWrist instruments) to existing *da Vinci* system owners, allowing for greater volume and breadth of procedures performed, and (iii) servicing previously sold *da Vinci* systems.

66. In June 2000, Intuitive had its initial public offering. That same year, the *da Vinci* system became the first robotic surgery system cleared by the FDA for some laparoscopic surgeries. In the following years, the *da Vinci* system's indications expanded to thoracoscopic surgery and certain cardiac, urologic, gynecologic, pediatric, and transoral procedures.

B. Intuitive Was and Is Subject to a Detailed FDA Regulatory Regime

67. Since the Company's inception, compliance with FDA regulations has been critical to Intuitive's success.

68. The *da Vinci* system is a "Class II" medical device, which makes it subject to an intermediate level of scrutiny and regulation by the FDA because FDA "general" controls cannot guarantee safety and effectiveness.

69. The *da Vinci* system, therefore, was subject to a rigorous approval process when it first came to market, and remains subject to an abbreviated approval process for each instance when the circumstances in which the device can be used (referred to as an "indication") is changed or expanded. The indications for which Class II medical devices, like the *da Vinci*, are approved must be clearly communicated on FDA regulated labels.

70. As Intuitive's 2011, 2012, and 2013 Annual Reports on Form 10-K all make clear, as the manufacturer of a Class II medical device designed to perform surgical procedures, Intuitive has always been subject to "extensive regulation" by the FDA. These FDA regulations include, among other things:

- "[T]he FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or 'off-label' uses";
- "[S]tringent complaint reporting and Medical Device Reporting regulations, which require[] that manufacturers keep detailed records of investigations or complaints

against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur";

- "[A]dequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest the same"; and
- "[T]he reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the [Act] that may pose a risk to health."

71. As is spelled out in the Company's Annual Reports for 2011, 2012, and 2013 (each of which were signed by all nine of the Director Defendants), Defendants recognized that "complying with FDA regulations is a complex process," and that the Company's failure to comply "could lead to an enforcement action that may have an adverse effect on [Intuitive's] financial condition and results of operations."

72. Defendants likewise recognized that the FDA could "institute a wide variety of enforcement actions, ranging from a regulatory letter to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or ban on the import or export of our products."

73. Intuitive has managed to comply with FDA reporting obligations concerning mislabeling and corrections in the past. For example, in January 2008, Intuitive successfully undertook a corrective action to fix a mislabeling issue on 1,136 of its Dissecting Forceps, one of the EndoWrist instruments.

C. Intuitive's Failure to Comply With FDA Regulations Has Been a Stain On Its Corporate Culture for Over a Decade

74. On April 12, 2001, less than a year after the *da Vinci* system received its first FDA approval, which indicated it for a subset of laparoscopic procedures, Intuitive received its first warning letter from the FDA (the "April 12, 2001 Warning Letter").

75. The FDA defines a FDA Warning Letter as: "a correspondence that notifies regulated industry about ***violations*** that [the] FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the [FDA] ***considers one or more products, practices, processes, or other activities to be a violation*** of the Federal Food, Drug,

and Cosmetic Act [(the 'Act')], its implementing regulations [or] other federal statutes. Warning Letters [are] only . . . issued for violations of regulatory significance, *i.e.*, those that ***may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected***" (emphasis added).

76. An FDA Warning Letter is the most serious agency communication and often the last step prior to the imposition of penalties including seizure, injunction, and/or civil monetary penalties. FDA Warning Letters presume that "officials in positions of authority" are "fully aware of their responsibilities."

77. The April 12, 2001 Warning Letter was addressed to Defendant Smith, who at the time was the CEO and a director of the Company, and currently serves as its Chairman. The April 12, 2011 Warning Letter stated that the FDA found that the Company had violated the Act and regulations by "mak[ing] misleading claims" on its website and in press releases that suggested that the *da Vinci* system had "general clearance, for [all] laparoscopic procedures," when it did not. The FDA also found that "Intuitive continues to promote the [*da Vinci* system] off-label for prostatectomy procedures as well as cardiac procedures . . . . Intuitive implies that the [*da Vinci*] system has use in a variety of applications that have not received agency clearance." The FDA found that, pursuant to the Act and regulations, "Intuitive's promotion of [the *da Vinci* system] for off-label uses . . . misbrands and adulterates" it.

78. The April 12, 2001 Warning Letter to Smith stated that it was Intuitive's "responsibility to ensure adherence to each requirement of the Act and regulations," and for "investigating and reviewing all materials to ensure compliance with applicable regulations." The April 12, 2001 Warning Letter also required Intuitive to "take prompt action to correct these violations . . . and ***to prevent similar violations in the future***" (emphasis added). The April 12, 2011 Warning Letter warned that "[f]ailure to promptly correct the[] violations [described in the April 12, 2001 Warning Letter] may result in regulatory action being initiated by [the] FDA without further notice." Possible repercussions to the Company could include "seizure, injunction and/or civil money penalties."

79. In addition to Defendant Smith, who at the time was the President, CEO, and a director of Intuitive, and is now Chairman of the Board, Defendants Guthart, Levy, Brogna, McNamara, Morales, and Rosa were all directors or employees of Intuitive when the FDA issued the April 12, 2001 Warning Letter. Despite the FDA's stern warning that the Defendants were responsible for "prevent[ing] similar violations in the future," and the fact that seven of the Defendants were with the Company at the time of the April 12, 2001 Warning Letter, Intuitive was marketing the *da Vinci* system for off-label uses as recently as 2013 (as discussed below).

80. In December 2002, about two years after receiving FDA approval for its first procedures, Intuitive received an FDA Form 483, warning it of reporting, correction, and removal violations (the "December 2002 Form 483").

81. According to the FDA, "[a] FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in [his or her] judg[]ment may constitute violations of the . . . Act [or] related Acts." The FDA Form 483 "***notifies the company's management of objectionable conditions.*** At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously" (emphasis added). Thus, the FDA discussed the 2002 Form 483, which reflected the FDA's finding of probable Act violations due to deficient reporting and corrective actions, with Intuitive's senior management. Since becoming a publicly traded company in 2000, Intuitive has received at least ***seven*** FDA Form 483s.

82. The December 2002 Form 483, which like the April 12, 2001 Warning Letter was addressed to Smith, found that the Company had conducted at least "***four unreported field corrections and removals***" that were "***not reported in writing to the FDA***" (emphasis added). For example, "[a] field correction of the DaVinci Surgical System, conducted based on the risk that a fire could occur during use, was not reported to the FDA." The FDA found that Intuitive had "determined that the event was MDR-reportable," but nevertheless, Intuitive claimed that its internal process of management review was sufficient. The FDA found that this internal process was deficient and likely violated the Act.

83. The December 2002 Form 483 specified that "[t]he observations noted . . . are not an exhaustive listing of objectionable conditions" and that "[u]nder the law, [Intuitive was] responsible for conducting ***internal self-audits*** to identify and correct any and all violations" (emphasis added).

84. In addition to Smith, Defendants Guthart, Levy, Brogna, Castello, McNamara, Morales, and Rosa were directors or employees of Intuitive when the Company received the December 2002 Form 483. Despite the FDA's stern warning that "[c]omplaint handling procedures for receiving, reviewing, and evaluating complaints ha[d] not been implemented," and the fact that eight of the Defendants were with the Company at the time of the December 2002 Form 483, the Defendants allowed for continued deficient FDA reporting, including through the very similar failure to disclose and document the October 2011 corrective and removal actions, as recently as 2013.

85. On February 19, 2008, Intuitive received an untitled letter from the FDA warning, once again, of the Company's reporting, correction, and removal violations.

86. Defendants Guthart, Smith, Halvorson, Levy, Loop, Rubash, Mohr, Brogna, Castello, Meltzer, McNamara, Morales, and Rosa were directors or employees of Intuitive when the Company received the untitled February 19, 2008 letter. Again and as discussed below, despite the fact that thirteen of the Defendants were with the Company at the time of the February 19, 2008 letter, the Defendants continued to allow Intuitive to undertake improperly disclosed and documented corrective and removal actions as recently as 2013.

D. Defendants Become Aware of a Dangerous Design Defect With the *da Vinci* System and Initiate Secret Corrective Action

1. The Defect

87. As discussed above, the tiny surgical implements used in connection with the *da Vinci* system are known as the EndoWrist instruments. The EndoWrist instruments are used to perform surgery inside the patient's body through the robotic arms controlled by the surgeon. At least one category of EndoWrist instruments – the "Advanced Energy Instruments" – employs an electrical charge to coagulate, cut, dissect, or cauterize tissue. For example, the Hot Shears Monopolar Curved Scissors (the "Scissors"), can, in addition to cutting tissue, cauterize incisions and wounds through the application of electricity. The electricity used by the Advanced Energy

Instruments is supposed to be contained by the Tip Cover, which is silicon and plastic sheath that insulates the rest of the metal instrument.

88. It is common practice for surgeons performing traditional surgery to clean their instruments mid-surgery by scraping tissue and fluids off of one tool with another. Not surprisingly, surgeons do the same with the EndoWrist instruments. However, due to a known design defect, intraoperative cleaning (*i.e.*, brushing the instruments against each other during a procedure) can crack or slit the Tip Cover insulating Advanced Energy Instruments such as the Scissors. If the Tip Cover fails, it can cause "arcing" – a term describing instances where the electricity running through the Advanced Energy Instrument escapes the intended area.

89. Arcing can burn soft tissue inside the patient's body during surgery. These burns can be very dangerous, and potentially fatal, particularly because arcing will frequently occur outside of the surgeon's field of vision, which is limited by the *da Vinci* console. Thus, the surgeon may be unaware that a dangerous condition even exists. Burns from arcing can lead to internal bleeding, sepsis, and puncturing or laceration of internal organs. *Bloomberg* reported in March 2013 that "[r]obot systems made by Intuitive . . . are linked to at least 70 deaths . . . since 2009."

90. A cannula is a small plastic tube that is inserted into the incision and through which the EndoWrist instruments pass into the patient's body. In May 2013, the FDA found that malfunctions of *da Vinci* system cannulas contribute to the arcing problem.

91. This design defect was beginning to become known in surgical circles by mid-2011. For example, in early 2011, doctors associated with The Ohio State University Medical Center Department of Urology published a study titled "Robotic instrument insulation failure: initial report of a potential source of patient injury" in the *Journal of Urology* – "the most widely read and highly cited journal in the field." The study "report[ed] [the authors'] experience[s] with failures in the accessory tip covers that insulate the monopolar robotic cautery scissor instruments and the patient injuries that ha[d] resulted." The study found that "[f]ailure[s] in robotic accessory tip covers can lead to patient complications," and that the "accessory tip cover failures were discovered . . . [at] a failure rate of 2.6%."

92. Similarly, in August 2011, doctors associated with the Hospital Quiron Madrid, Santa Creu I Sant Pau, Barcelona, and Mayo Clinic Arizona published a study titled "Insulation failure in robotic and laparoscopic instrumentation" in the *American Journal of Obstetrics & Gynecology* – a top journal that was "first in total citations" in the field. The study found that insulation failure (which was described as an "important cause of electrosurgical injury in minimally invasive surgery that results from damage to the coating that insulates the instrument") occurred in "robotic" laparoscopic surgery at a rate of ***approximately 4-1*** when compared to traditional laparoscopic procedures. The study also found that "there [was] a high incidence and prevalence of [insulation failure] in robotic and laparoscopic electrosurgical instruments, ***even when they were tested according to the manufacturer's voltage specifications***" (emphasis added).

93. As is set forth in more detail below, Intuitive failed to disclose the true extent of health and safety concerns inherent to the *da Vinci* system. When the truth ultimately became known in March 2013, the Company's stock price plummeted and Intuitive suffered a sharp revenue decline.

2. Medical Device Reporting Requirements

94. FDA Regulation 21 C.F.R. 803 creates a regime of mandatory reporting for manufacturers, importers, and device users of certain medical device-related adverse events and product problems to the FDA.

95. In the event that a medical device "may have caused or contributed to a death or serious injury," a user of the device (*i.e.* a hospital) is ***required*** to make a "Medical Device Report" (an "MDR") of the event to the manufacturer within 10 business days of becoming aware of the adverse event. Thus, within 10 business days, Defendants would have known of each adverse event discovered by *da Vinci* users who themselves complied with FDA regulations.

96. A manufacturer is ***required*** to make an MDR reporting any death or serious injury to the FDA within 30 calendar days of becoming aware of the adverse event. A manufacturer is also required to investigate any adverse event to reach an understanding of its underlying causes, and to supplement any initial MDR sent to the FDA as appropriate.

97. In the 2013 Form 483 (discussed below), the FDA found that *da Vinci* system users who experienced adverse events (including serious injuries and fatalities) sent Intuitive: 134 complaints and Intuitive filed 82 MDRs related to arcing between January 2010 and December 2011; 17 complaints related to defective cannulas (which, as discussed below, the FDA found were a root cause of the defective Tip Covers) between January 2010 and September 2011; and 13 complaints and Intuitive filed five MDRs related to off-label marketing of the *da Vinci* system between July 2009 and October 2011.

98. Thus, Defendants knew of the Tip Cover design defect, which implicated the safety of Intuitive's ***sole product***, at least as early as January 2010, and that off-label marketing was an ongoing problem as early as July 2009.

99. Scholarly sources also found that Intuitive was aware of problems with the *da Vinci* system (through MDRs reported by users to Intuitive) for a similarly long time. In 2013, doctors associated with Johns Hopkins Hospital and the University Hospitals in Cleveland published a study titled "Underreporting of Robotic Surgery Complications" in the *Journal for Healthcare Quality* – "the first choice for creative and scientific solutions in the pursuit of healthcare quality." The study reported that at least by August 1, 2012, Intuitive was aware of 71 deaths and 174 nonfatal injuries associated with the *da Vinci* system.

3. The October 2011 Secret Recalls

100. Although the FDA and scholarly sources found that Intuitive was aware of high rates of MDRs, fatalities, and serious injuries associated with the *da Vinci* system in 2009, 2010, 2011, and the first half of 2012, Intuitive systematically underreported and downplayed these events to the FDA and public.

101. Intuitive's inadequate reporting, and, in fact, conscious manipulation of its MDRs, were the product of the Defendants' failure to discharge their fiduciary duties to Intuitive and its stockholders, including by failing to implement appropriate internal controls for FDA reporting. Instead of ensuring that Intuitive had an appropriate system of internal controls, rectifying MDR reporting issues, and addressing the health and safety concerns presented by the *da Vinci* system with the FDA and the public, and despite the FDA's admonishments in 2002 and 2008 regarding

Intuitive's similar prior failures to adequately report corrective actions, Defendants authorized or deliberately turned a blind eye to a program of covert recalls. In doing so, Intuitive, under Defendants' direction, failed to report these corrective actions to the FDA, which constituted ***another***, independent and distinct reporting violation.

102. On October 10, 2011, in response to complaints, MDRs, and injuries caused by the *da Vinci* system's Tip Cover accessory, Intuitive, under Defendants' direction, sent a letter to hospitals and surgeons to whom it had sold the *da Vinci* system, providing "suggestions and recommendations for the proper use of instruments with [T]ip [C]overs" (the "Tip Cover Corrective Action Letter"). The FDA found in 2013 that the Tip Cover Corrective Action Letter was a "Class II" recall, taken to reduce the risk of health posed by a regulated device. Pursuant to FDA regulation 21 C.F.R. 806.10(b), Intuitive was ***required*** to report any corrective action (such as the Tip Cover Corrective Action Letter), taken to reduce a risk to health posed by a device (such as the arcing problem), within 10 business days. The Tip Cover Corrective Action Letter was not disclosed to the FDA, which only learned of this covert recall years later during its inspection of Intuitive's facilities in April and May 2013. The FDA also found that this corrective action was a response to the 134 complaints received and 82 MDRs filed by Intuitive related to arcing between January 2010 and September 2011.

103. Intuitive, under Defendants' direction, also undertook two other covert corrective actions in October 2011. On October 13, 2011, Intuitive, under Defendants' direction, sent a letter to *da Vinci* owners stating that the *da Vinci* system was ***not*** approved for thyroidectomies, despite Intuitive's prior promotions to the contrary (the "Thyroidectomy Corrective Action Letter"). Despite the FDA's admonishment in 2001 regarding a similar incident of off-label marketing of the *da Vinci* system, Defendants nevertheless caused Intuitive to continue to make misleading and potentially dangerous claims suggesting that the *da Vinci* system was approved for thyroidectomies, when it was not.

104. The FDA found in 2013 that the Thyroidectomy Corrective Action Letter was likewise a "Class II" recall taken to reduce the risk of health posed by a regulated device. Thus, Intuitive was ***required*** to report it to the FDA within 10 business days. The Thyroidectomy

Corrective Action Letter was not disclosed to the FDA, which only learned of this covert recall years later during its inspection of Intuitive's facilities in April and May 2013. The FDA also found that this corrective action was a response to the 13 complaints received and five MDRs filed by Intuitive related to off-label marketing of the *da Vinci* system for thyroidectomies between July 2009 and October 2011.

105. On October 17, 2011, Intuitive sent a letter to *da Vinci* owners "providing information" regarding the inspection of cannulas, the flushing of instruments, and the transportation of *da Vinci* systems between buildings (the "Cannula Corrective Action Letter"). The FDA found in 2013 that the cannula inspection issue was related to the Tip Cover defect, and thus the Cannula Corrective Action Letter was also a "Class II" recall taken to reduce the risk of health posed by a regulated device. Thus, Intuitive was ***required*** to report it to the FDA within 10 business days. The October 17, 2011 Cannula Letter was not disclosed to the FDA, which only learned of this covert recall years later during its inspection of Intuitive's facilities in April and May 2013. The FDA also found that this covert corrective action was a response to the 17 complaints received by Intuitive between January 2010 and September 2011 related to defective cannulas (which, as discussed below, the FDA found were a root cause of the defective Tip Covers).[4]

[redacted]

[4] As found by the FDA in its 2013 Form 483, Intuitive conducted yet another covert recall on January 24, 2013, when it, under Defendants' direction, sent a letter to clients attaching an updated user manual "clarifying" that, despite prior representations to the contrary, the *da Vinci* system was not indicated for transoral surgery on certain groups of patients, including pediatric patients. As discussed below, the FDA found that the vagueness in the previous Manual represented a health risk to pediatric patients and the clarification was a Class II recall. This is yet another example of Intuitive's repeated off-label marketing.

[redacted]

E. The FDA Investigates Intuitive's Failure to Comply With the Federal Food, Drug, and Cosmetic Act and FDA Regulations

1. The FDA Investigates Intuitive, Resulting in a Dramatic Adjustment to Intuitive's FDA Reporting Practices

108. In the wake of reports in the surgical community regarding the health and safety implications of the *da Vinci* system, top Intuitive officials had a meeting with FDA officials in September 2012. At that meeting, the FDA warned against misclassifying adverse events for the purposes of MDR reporting. At the time, Intuitive did not even disclose that this meeting with the FDA occurred, much less the substance of the meeting.

109. As a result of the September 2012 meeting, Defendants began to change the Company's MDR reporting practices (without acknowledging to the FDA or to the public, including shareholders, how deficient the Company's prior practices had been).

110. The FDA's admonishments regarding Intuitive's reporting practices, and the Company's consequent change in practices, dramatically increased the number of MDRs filed related to the *da Vinci* system. In 2013 alone, Intuitive filed more *da Vinci* system-related MDRs than it had in the entire 2000-2012 period.

111. Intuitive later conceded that, prior to September 2012, the Company had: (i) underclassified some serious injuries as "other," in an apparent effort to avoid triggering mandatory MDR reporting to the FDA; (ii) downplayed adverse events in the MDRs that it did file to create a misleading impression of the significance of the design defect; and (iii) failed to properly address some complaints regarding adverse events altogether.

[redacted]

[redacted]

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113. Scholarly sources likewise confirm that Intuitive was misreporting MDRs prior to September 2012. For example, the *Journal for Healthcare Quality* study, discussed above, searched public filings for lawsuits related to *da Vinci* system fatalities. The study found that, out of 70 lawsuits identified, over 10% had never been reported to the FDA via MDRs, or were reported erroneously. The study concluded that "[t]here are several potential reasons for underreporting .... [T]he increased likelihood of electrical arcing [is a] potential risk[] associated with robotic surgery. Using meticulous precautions, a skilled surgeon can generally prevent these risks from harming a patient. However, in reality, when ***mistakes are easier to make*** with one approach versus another . . . ***they are more likely to occur***. Second, there is little oversight regarding reporting. Finally, ***there is little incentive to improve reporting practices***. Better reporting systems can help elucidate risk factors associated with injuries" (emphasis added).

114. The FDA quickly determined that the informal September 2012 meeting was not, without more, going to resolve Intuitive's regulatory problems, including disclosure of the true

number of injuries and deaths caused by the *da Vinci* system. In January 2013, the FDA began a safety probe into the *da Vinci* system. Unwilling to rely on Intuitive's reporting of adverse events, the FDA's probe involved actually surveying and interviewing surgeons and facilities that used the *da Vinci* system regarding problems or adverse events they had encountered.

2. The Public Learns That Intuitive Is Under Regulatory Scrutiny For Underreporting Adverse Events, Resulting In A Sharp Stock Price Decline

115. On February 28, 2013, *Bloomberg* broke the story of the FDA's investigation into Intuitive in an article titled "Intuitive Robot Probe Threatens Trend-Setting Surgeries." The article stated that "[t]he safety of robots made by Intuitive . . . is being probed by U.S. regulators, raising questions about the prospects of one of the hottest technologies in health care." According to *Bloomberg*, "[t]he [FDA] asked surgeons at key hospitals to list the complications they may have seen with the machines . . . . The doctors were also surveyed on which surgeries the robots might be most and least suited for." *Bloomberg* thought that "[t]he answers may sway debate on whether robotic surgeries promoted as being less invasive are worth the extra cost." Thus, "[t]he findings may also determine the outlook of Intuitive" because "[t]he da Vinci surgical system and related products generated most of [Intuitive's] $2.2 billion in revenue in 2012." An FDA spokeswoman told *Bloomberg* that "[w]hat the agency [was] trying to determine [was] ***whether a rise seen in incident reports sent to the [FDA] [we]re 'a true reflection of problems' with the robots, or the result of other issues***'" (emphasis added). The FDA found it "***difficult to know why the reports ha[d] increased***" (emphasis added). In other words, the FDA was trying to determine the cause of a spike in adverse incident reports that came in the months following its meeting with Intuitive officials regarding the Company's reporting practices.

116. Upon publication of the February 28, 2013 *Bloomberg* article, Intuitive's stock price declined over 11%, from $573.52 to $509.89.

117. On March 5, 2013, *Bloomberg* published a detailed article entitled, "Robosurgery Suits Detail Injuries as Death Reports Rise," which uncovered health risks associated with the *da Vinci* system and the swelling number of resultant lawsuits. For example, *Bloomberg* published that "[r]obot systems made by Intuitive . . . are linked to at least 70 deaths . . . since 2009." *Bloomberg*

thought that "tough new questions about safety raised in lawsuits and in adverse incident reports to U.S. regulators may threaten the company's growth." The article also detailed the story of Kimberly McCalla, who underwent surgery for early-stage cervical cancer using the *da Vinci* system, only to pass away from small bowel damage after several emergency procedures related to a lacerated "iliac artery near the original operation."

118. On March 13, 2013, Intuitive was forced to issue a statement commenting on the negative press coverage related to the safety of the *da Vinci* system and "its medical device reporting practices" (the "March 13, 2013 Press Release"). In the March 13, 2013 Press Release, Intuitive conceded that the Company's previous adverse event reporting practices were deficient. Intuitive stated that "the noted rise [in MDRs filed by Intuitive] does not reflect a change in product performance but ***rather a change in MDR reporting practices. In September 2012, Intuitive . . . revised its MDR practices, resulting in increased reports of device malfunction MDRs***" (emphasis added). Specifically, the Company's "administrative change in how MDRs [were] reported . . . [would] result in an increase in events in the 'serious injury' subcategory and a corresponding decrease in the 'other' subcategory." As discussed, adverse events categorized as "other" need not be reported to the FDA, while adverse events categorized as "serious injury" ***are subject to mandatory MDR reporting.*** Intuitive has never provided any public justification for the pre-September 2012 improper reporting practices.

119. On March 14, 2013, the President of ACOG, Dr. James T. Breeden, published a "Statement on Robotic Surgery" on behalf of ACOG. Dr. Breeden wrote that "robotic surgery is not the only or best minimally invasive approach . . . . It is important to separate the marketing hype from the reality."

120. Between February 27 and March 15, 2013, as more and more news sources reported on the serious regulatory issues at Intuitive, culminating in the March 13, 2013 Press Release, Intuitive's stock price fell by nearly ***20%*** from $573.52 per share to $459.44 per share.

3. The 2013 Form 483

121. As the facts regarding the true hazards of the *da Vinci* system started to reach the FDA and the public, as reflected by the increasing number of serious adverse events reported,

regulatory scrutiny increased. From April 1 through May 30, 2013, the FDA investigated Intuitive's facilities. At the conclusion of the investigation, the FDA issued another Form 483 which contained the FDA's determination that Intuitive may have violated the Act and other laws or regulations through improperly disclosed and documented corrective and removal actions (the "2013 Form 483") – just as it did in 2002 and 2008.

122. The 2013 Form 483 was addressed to Defendant Guthart, and "list[ed] observations made by the FDA . . . during the inspection of [Intuitive's] facility." In the 2013 Form 483, the FDA observed four "objectionable conditions."

123. Observation 1 was that Intuitive took "four field actions," each of which were "[a] correction or removal, conducted to reduce a risk to health posed by" the *da Vinci* system, which were "not reported in writing to the FDA" as required by regulation. Specifically, the FDA found that:

- "On 10/10/2011, Intuitive . . . sent out a letter to da Vinci clients with suggestions and recommendations for the proper use of instruments with tip covers and for the correct generators that should be used with monopolar instruments. This action was not reported to the San Francis[c]o District Recall Coordinator. This correction was in response to complaints and MDRs for arcing through damaged tip covers that caused patient injury. ***Between January 2010 and December 2011, Intuitive . . . received 134 complaints and filed 82 MDRs related to tip cover issues"*** (emphasis added).

- "On 10/13/2011, Intuitive . . . sent out a letter to da Vinci clients that the da Vinci surgical systems ***are not cleared for thyroidectomy indication***. This action was not reported to the San Francis[c]o District Recall Coordinator. The thyroidectomy indication was promoted by Intuitive" but had not been approved by the FDA. "***Between July 2009 and October 2011, Intuitive . . . received 13 complaints and filed 5 MDRs related to thyroidectomies performed with the da Vinci system***" (emphasis added).

- "On 10/17/2011, Intuitive . . . sent out a letter to da Vinci clients with information for inspecting instrument cannulas, proper flushing of instruments, and the proper transportation of the da Vinci between buildings. This action was not reported to the San Francis[c]o District Recall Coordinator. ***Between January 2010 and September 2011, Intuitive . . . received 2 complaints related to instrument flush ports and 17 complaints related to cannulas***. There were no MDRs directly associated with these complaints, however some of these issues ***had been previously identified as root causes in other complaints that gave rise to MDRs (for example, damage to the integrity of a tip cover due to defective cannulas was identified as one of the root causes for arcing that resulted in patient injuries***). As such these issues represent a risk to the health of patients" (emphasis added).

- "On 01/24/2013, Intuitive . . . sent out a letter and . . . User Manual Addendum . . . to clients [that] clarified the types of patients and conditions for which da Vinci

> [transoral surgery] is indicated. [T]he new version of the [Manual] warns that da Vinci [transoral surgery] is not indicated for pediatric patients, therefore ***the vagueness in the previous version . . . represented a health risk to pediatric patients"*** (emphasis added).

124. Observation 2 was that Intuitive failed to report "[i]llnesses or injuries that . . . occurred with use of devices subject to the corrections and removals" described in Observation 1. For example, Intuitive "failed to report that there were 5 MDRs associated with the field action taken on 10/13/2011 (Thyroidectomy indication withdrawal)." In the report made to the San Francisco District Coordinator on April 11, 2013, Intuitive represented that there had been ***zero*** such MDRs.

125. Intuitive's failure to properly report corrective actions to the FDA was particularly brazen, given the FDA's December 2002 Form 483 and February 19, 2008 letter regarding substantially the same violative conduct and instructing Intuitive to refrain from such behavior.

126. Observation 3 was that Intuitive did not have "adequately established" "procedures for design change." For example, "Intuitive . . . did not document the decision to add a thyroidectomy indication to the da Vinci system . . . . At the time that this decision was made there were no procedures in place to document this design change issue . . . . [T]here was no retrospective analysis done to determine how to prevent this error from recurring, or to assess if the decision to add a thyroidectomy indication to the da Vinci system . . . , or any other regulatory decisions made for any other design changes [before modification to Intuitive's policies] should have been reassessed."

127. Intuitive's wrongful promotion of off-label uses for the *da Vinci* system was also particularly brazen, given the FDA's April 12, 2001 Warning Letter regarding substantially the same violative conduct, which instructed Intuitive to refrain from such behavior.

128. Observation 4 was that Intuitive did not have "adequately documented" "[d]esign input requirements." Specifically, "the user need for intrasurgical cleaning of surgical instruments was not part of the user needs included in the design of surgical instruments . . . that are commonly known to need cleaning during surgery." In other words, Intuitive failed to consider that surgeons might engage in common intrasurgical cleaning practices. Intuitive then concealed that this design defect put patients at risk. The FDA found that ***"Intuitive . . . ha[d] received complaints of arcing***

of energized surgical instruments as a result of surgeons cleaning off instruments intrasurgically by scraping them across other instruments. In the case of energized surgical instruments, such as [the Scissors], the scraping led to tears or holes in protective [T]ip [C]overs that led to arcing that in turn led to injuries to patients" (emphasis added).

129. Just as it had in the December 2002 Form 483, the FDA specified that "[t]he observations noted . . . are not an exhaustive listing of objectionable conditions" and that "[u]nder the law, [Intuitive was] responsible for conducting ***internal self-audits*** to identify and correct any and all violations" (emphasis added). Intuitive was encouraged to discuss any corrective action, or plan to implement any corrective action, with the FDA.

4. The July 16, 2013 FDA Warning Letter

130. On July 16, 2013, the FDA issued another warning letter to Intuitive (the "July 16, 2013 Warning Letter"), which was addressed to Defendant Guthart.

131. In the July 16, 2013 Warning Letter, the FDA found that several Intuitive devices, including the Tip Cover and Cannula were "***misbranded*** devices . . . in that [Intuitive] failed or refused to furnish material or information respecting the device that [was] required."

132. Specifically, the July 16, 2013 Warning Letter found that each of the three corrective actions taken in October 2011 and the corrective action taken in January 2013 were "Class II Recalls." "Though [each] field action was undertaken to reduce a risk to health posed by the device, [Intuitive] failed to report the field action to the FDA as required" pursuant to regulation "within 10 working days of any correction or removal of a device." Echoing the 2013 Form 483, the July 16, 2013 Warning Letter stated:

- "In October 2011, Intuitive . . . initiated a field correction by sending letters to da Vinci Surgical System clients with suggestions and recommendations for the proper use of the Tip Cover Accessory and for the correct generators that should be used with monopolar instruments. This correction ***was in response to complaints and medical device reports (MDRs) for arcing through damaged tip covers that caused patient injuries"*** (emphasis added).

- "In October 2011, Intuitive . . . initiated a separate field correction by sending letters to da Vinci Surgical System clients to notify them that the da Vinci Surgical Systems promoted fc thyroidectomy indications [was] ***not cleared for that use***. [Intuitive was] ***aware of complaints and MDRs related to thyroidectomies performed with the da Vinci Surgical System"*** (emphasis added).

- "In October 2011, Intuitive . . . initiated a separate field correction by sending letters to da Vinci Surgical System clients with information for inspecting the instrument cannulas, proper flushing of the instruments, and proper transportation of the da Vinci Surgical System between buildings."

- "In January 2013, Intuitive . . . initiated a field correction by sending letters and [a] replacement user manual addendum . . . to da Vinc[i] Surgical System clients. The replacement addendum include[d] changes to the types of patients and conditions for which da Vinci [transoral surgery was] indicated, such as [a] warning against use in pediatric patients."

133. Previously, on June 17, 2013, Intuitive had responded to the FDA's findings in the 2013 Form 483, in which it argued that the Company's standard operating procedures gave it the authority to determine that its corrections, removals, and labeling would be reviewed by a third party expert, instead of the local FDA district recall coordinator. The FDA found that Intuitive's response was "incomplete and inadequate."

134. The FDA also found that several *da Vinci* system components, including the Tip Cover and Cannula were "***adulterated*** devices . . . in that the methods used in, or the facilities or controls used for its manufacture . . . are not in conformity with the Current Good Manufacturing Practice . . . requirements for devices," which are set by regulation.

135. Specifically, the FDA found that the "[d]esign input requirements [for the Tip Cover and Cannula] were not adequately documented." In other words, Intuitive was aware that the design of the Tip Cover and Cannula could cause arcing, but failed to take adequate steps to try and develop an alternative design or provide sufficient warning to surgeons. The FDA found that "[Intuitive] informed [the FDA] investigator that [it was] aware of patient injuries associated with intraoperative cleaning of energized instruments such as the Monopolar Curved Scissors and Fenestrated Bipolar Scissors as evidence by at least [134] complaints and 82 MDRs during the calendar years 2010 and 2011 . . . . ***[Intuitive] also informed [the FDA] investigator that [it was] aware that cleaning instruments inside patients during surgery is a common practice*** . . . . When [the FDA] investigator] asked [Intuitive] to provide the design input documentation and design resolution of this known user need [it] failed to provide the requested documentation" (emphasis added).

136. Intuitive's response with respect to this violation was also found to be lacking. Instead of providing documentation of its "design control processes" with respect to the issue raised

by intrasurgical cleaning, Intuitive "d[id] not provide a response to the root cause of this critical missing design input in [its] design documentation."

137. The FDA warned Intuitive that "[f]ailure to correct [the violations described in the July 16, 2013 Warning Letter] may result in regulatory action being initiated by the FDA without further notice. [Possible] actions include[d], but [were] not limited to, seizure, injunction, and/or civil money penalties." The FDA also warned that it might advise "federal agencies . . . of the issuance of Warning Letters about devices so that they may take this information into account when considering the awarding of contracts."

138. Intuitive was warned that it alone was charged with the "responsibility to ensure compliance with applicable laws and regulations," and that it needed to provide the FDA with a prompt response regarding steps to fix the violations, "as well as an explanation of how [Intuitive] plan[ned] to prevent these violations, or similar violations, from occurring again."

139. The FDA pointed out that it had "previously informed [Intuitive] of [its] correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002." Additionally, the FDA had previously warned of the ramifications of off-label marketing in its April 12, 2001 Warning Letter.

140. The FDA explicitly noted that the July 16, 2013 Warning Letter was "not intended to be an all-inclusive list of the violations at [Intuitive]." Rather, these issues "may be symptomatic of serious problems in [Intuitive's] manufacturing and quality management systems." Thus, Intuitive was responsible for "investigat[ing] and determin[ing] the causes of the violations, and tak[ing] prompt actions to correct the violations and bring the products into compliance."

141. Intuitive announced that the FDA issued the July 16, 2013 Warning Letter on July 18, 2013. Intuitive's stock price declined almost 7% from $421.47 to $392.67 on this news – marking the first time that Intuitive stock dipped under $400 per share in nearly two years.

[redacted]

142. During the Relevant Period, Defendants knowingly caused and permitted the Company to fail to comply with mandatory MDR and corrective action reporting requirements and engage in off-label marketing, thereby exposing the Company to major legal and regulatory risk, including products liability claims, insurance fraud claims, and enforcement procedures by the FDA and other regulators. Defendants were aware of FDA reporting and off-label marketing issues, but had failed to implement appropriate internal controls previously, failed to appropriately resolve the issues on an expedited basis (and instead tried to hide the issues), and failed to implement appropriate internal controls prospectively.

143. On March 25, 2014, the Demand Letter was served on the Company. [redacted]

[redacted]

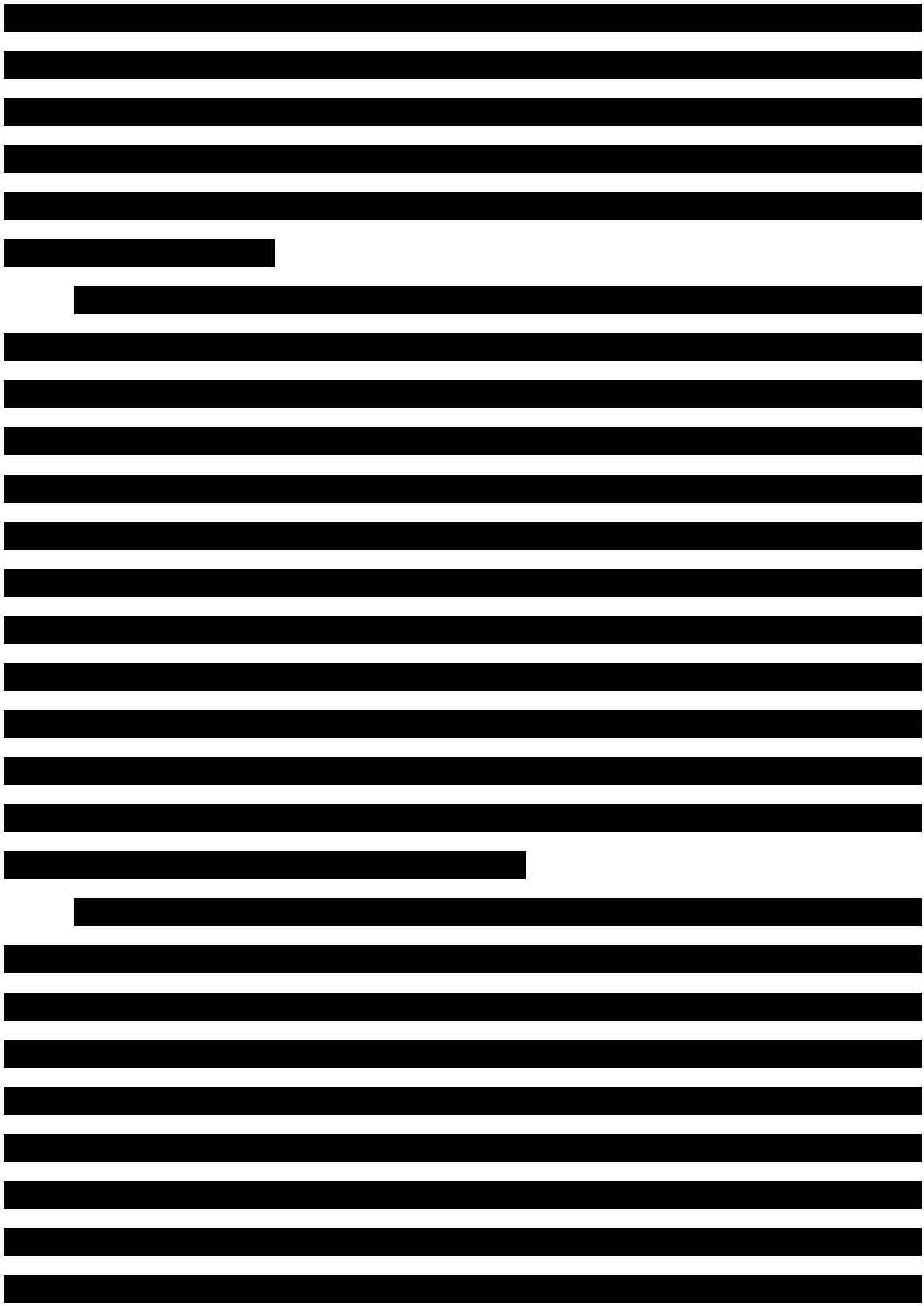
[5] The March 25, 2014 §220 Demand Letter demanded, *inter alia*, all Board materials reflecting or concerning:

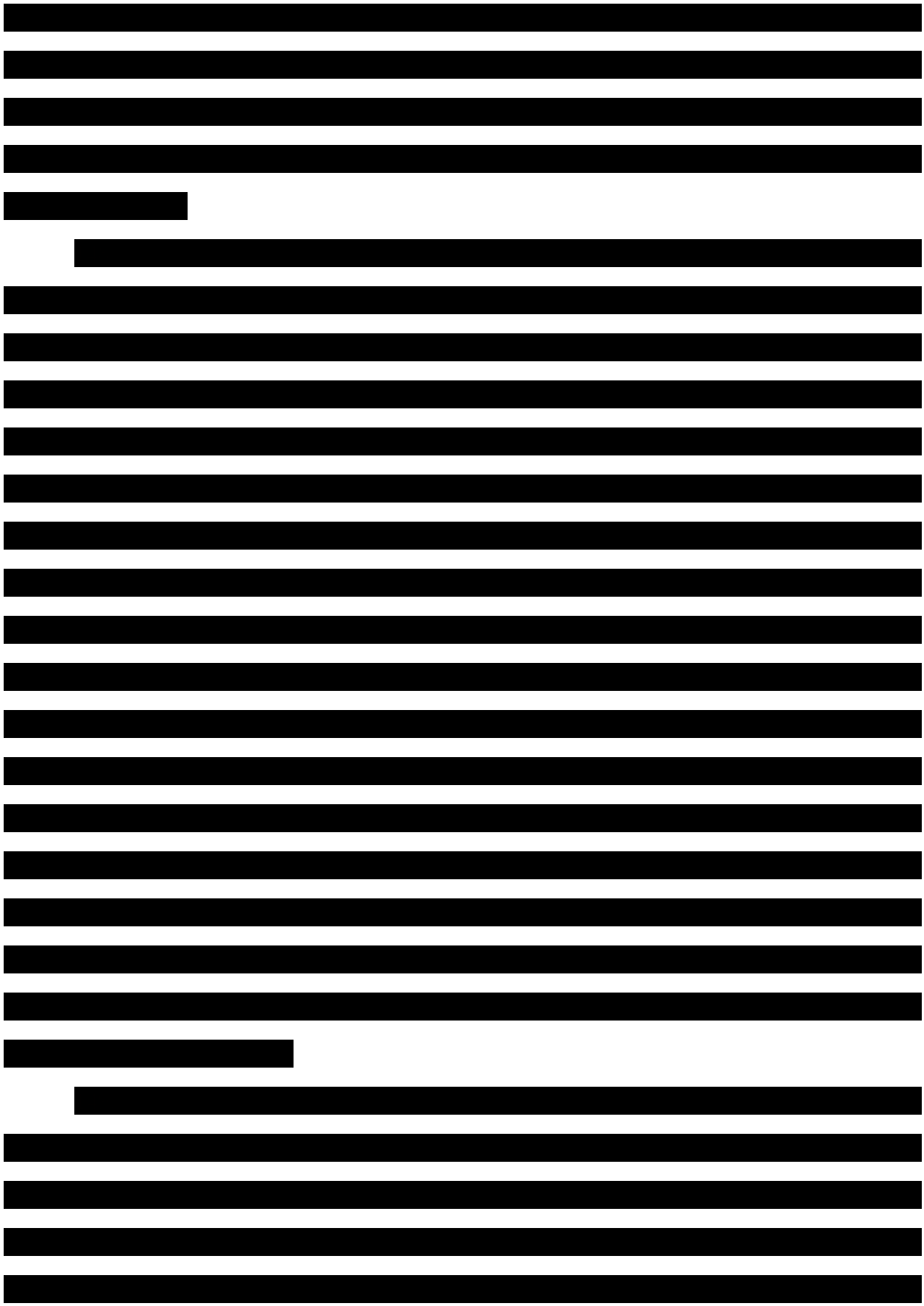
> "[T]he Company's controls, procedures and policies (including handbooks, instruction manuals or other guides provided to employees or representatives) regarding the Company's recording and reporting of adverse events arising from its products, and/or recalls of its products, including the da Vinci Surgery system, including any materials reflecting any assessment by the Board of the effectiveness of its controls, procedures and policies or inquiry into instances of non-compliance with those controls, procedures and policies";
>
> "[T]he Board's investigation (if any) into the assertions made by the FDA in the [2013] Form 483 and the [July 16, 2013] Warning Letter";
>
> "[A]ny discussion, consideration, evaluation, investigation and/or decision of the Board or any committee thereof regarding (a) the recalls described in the [2013] Form 483 and [July 16, 2013] Warning [L]etter; (b) the reasons for each recall; (c) the procedures to be followed for the recalls; (d) all discussions and/or advice

[redacted]

concerning the FDA or other regulatory requirements related to the recalls, including but not limited to reporting, filing and/or notice requirements; and (e) responses to the [2013] Form 483 and/or [July 16, 2013] Warning Letter"; and

"[A]ny discussion, consideration, evaluation, investigation and/or decision of the Board or any committee thereof regarding (a) under-report[ing] or misreporting of adverse events; (b) the Company's meeting with the FDA in September 2012; (c) the procedures to be followed for reporting adverse events; and (d) all discussions and/or advice concerning the FDA or other regulatory requirements related to the reporting of adverse events, including but not limited to reporting, filing and/or notice requirements."





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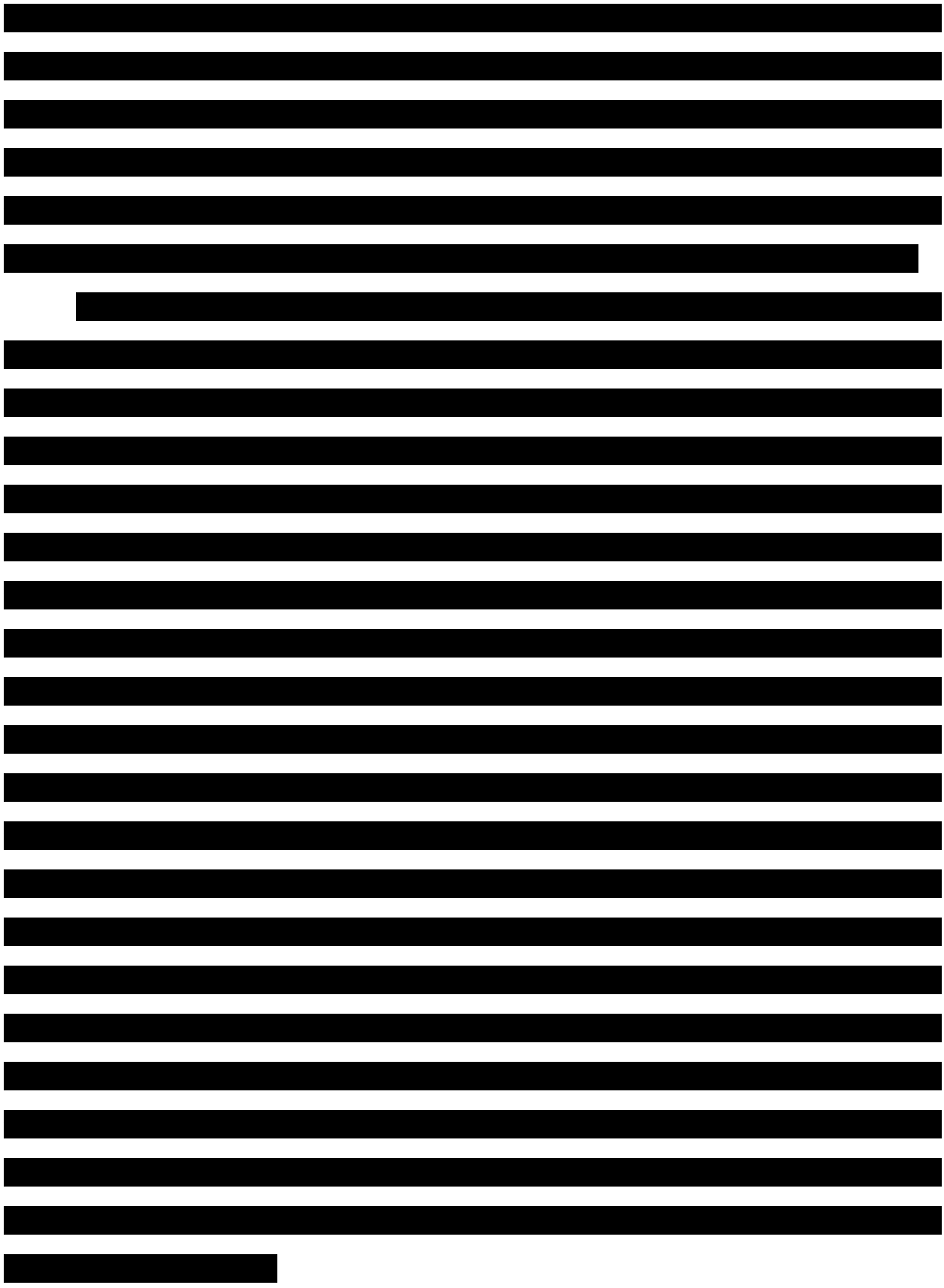

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G. Intuitive's Insurance Carriers Sue to Invalidate Products Liability Insurance Policies Due To Defendants' Malfeasance

156. On October 21, 2013, IUIC sued Intuitive in the Northern District of California seeking to rescind Intuitive's products liability insurance coverage due to misrepresentations in the number of products liability claims Intuitive was facing.

157. On December 16, 2013, NSIC (together with IUIC, the "Insurer Plaintiffs") sued Intuitive in a substantially similar lawsuit in the Northern District of California.

158. In January 2013, Intuitive approached the Insurer Plaintiffs about entering into insurance policies covering up to $15 million in payments and defense costs per products liability occurrence (subject to aggregate limits and deductibles) for a policy period of March 1, 2013 through March 1, 2014. Both Insurer Plaintiffs requested "loss runs" from Intuitive, showing the number of claimants who made claims on Intuitive's prior insurance policies over the course of a number of years. The loss runs provided by Intuitive showed very modest numbers of claims. For example, the loss run provided to Illinois for the policy period March 1, 2011 through March 1, 2012

showed nine claims, while the loss run provided to Illinois for the policy period March 1, 2012 through March 1, 2013 showed 25 claims.

159. The loss runs (and the rest of Intuitive's insurance applications to each Insurer Plaintiff) failed to disclose that Intuitive had entered into tolling agreements with several products liability claimants' attorneys, or that the total number of claimants was rising swiftly. The tolling agreements provided that the applicable statute of limitation for each individual claimant would be tolled for a period of three to six months in exchange for the individual's agreement that, if he or she ultimately filed a lawsuit, it would be in certain agreed upon venues.

160. The existence of the tolling agreements was not disclosed until Intuitive filed its Q1 2013 10-Q on April 19, 2013, although Intuitive has admitted in answering the Insurer Plaintiffs' complaints that Intuitive "knew its counsel had been entering into tolling agreements in January and February 2013." The policies sold by the Insurer Plaintiffs to Intuitive became effective in March 2013.

161. The Insurer Plaintiffs' lawsuits allege that the terms (including the price) of the policies they issued to Intuitive depended upon the accuracy of Intuitive's representations in its insurance applications, including that the loss runs reflected the Company's exposure.

162. Thus, after disclosure of the secret tolling agreements, the Insurer Plaintiffs sued to rescind Intuitive's products liability coverage on the grounds that Intuitive materially misrepresented the extent of its products liability exposure.

163. Defendants' conduct in misrepresenting or failing to prevent the misrepresentation of Intuitive's products liability exposure to the Insurer Plaintiffs harmed Intuitive because the Company may not be able to rely on its insurance policies as a means of satisfying any adverse judgments against the Company or settlements with claimants.

164. The March 25, 2014 Demand Letter demanded "[a]ll Board Materials that reflect any discussion, consideration, evaluation, investigation and/or decision of the Board or any committee thereof regarding (a) the insurance policies at issue in the *Navigators Specialty Insurance Company v. Intuitive Surgical* . . . and *Illinois Union Insurance Company v. Intuitive Surgical* . . . lawsuits; (b)

the accuracy of the information provided with respect to these insurance policies; and (c) the Board's involvement and/or oversight in seeking and/or applying for these insurance policies."

165. Defendants breached their fiduciary duties by failing to discuss, consider, evaluate, or investigate the veracity of statements made to the Insurer Plaintiffs and by failing to prevent or address false statements being made to the Insurer Plaintiffs. In particular, Defendant Guthart (as the Company's CEO), Defendant Mohr (as the Company's CFO) and Defendant Meltzer (as the Company's General Counsel) should have been vigilant to ensure that the Company did not jeopardize the validity of its liability insurance coverage, given their knowledge of the many potential product liability claims that the Company faced and the tolling agreements in place.

H. Throughout the Relevant Period, Defendants Make, or Cause Intuitive to Make, Materially False and Misleading Statements and Omissions Regarding the Company's Regulatory Compliance, Demonstrating That They Understood, But Failed to Execute, Their Regulatory Obligations

166. Throughout the Relevant Period, Defendants caused the Company to make periodic filings to the SEC, including its: (i) 2011 10-K, filed on February 6, 2012, (ii) Q1 2012 10-Q filed on April 19, 2012, (iii) Q2 2012 10-Q filed on July 23, 2012, (iv) Q3 2012 10-Q filed on October 18, 2012, (v) 2012 10-K filed on February 4, 2013, and (vi) Q1 2013 10-Q filed on April 19, 2013 (collectively, the "Periodic Filings"). Each of the Periodic Filings included nearly identical, boilerplate "risk factors" which are intended to apprise stockholders of potential risks to Intuitive's future prospects.

167. These risk factors demonstrate that Defendants knew and understood the Company's regulatory responsibilities, and the severe ramifications of noncompliance. But, as is discussed throughout, Defendants failed in their obligations.

168. Specifically, each of the Periodic Filings acknowledged that Intuitive's "products and operations are subject to extensive and rigorous regulation by the FDA, the State of California and countries or regions in which we market our products . . . . We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory documentation of our products." The Periodic Filings list specific FDA regulations, including that for MDR reporting and corrective actions.

169. Each of the Periodic Filings also warned stockholders that "complying with FDA regulations is a complex process, and [Intuitive's] failure to comply fully could subject [it] to significant enforcement actions. Because [Intuitive's] products including the *da Vinci* Surgical System, are commercially distributed, numerous postmarket regulatory requirements apply, including . . . the FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or 'off-label' uses'; the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to occur; adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest the same; and the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the [Act] that may pose a risk to health."

170. Each of the Periodic Filings also warned that "[i]f the FDA finds that [it] failed to comply, [the FDA] can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or ban on the import or export of our products. Failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on [Intuitive's] financial condition and results of operations."

171. Each of the Periodic Filings also warned stockholders that "if defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer. Our products incorporate . . . electrical components . . . any of which can contain errors or failures . . . . In addition, new products or enhancements may contain undetected errors or performance problems . . . . We cannot assure that our products will not experience component aging, errors or performance problems in the future." Intuitive warned that "flaws or performance problems" could result in, among other things, "loss of revenue; . . . damage to [Intuitive's] reputation; product recalls; regulatory actions; . . . [and] product liability claims."

172. Each of the Periodic Filings also warned stockholders that "the use of our products could result in product liability and negligence claims that could be expensive, divert management's attention and harm our business. [Intuitive's] business exposes [it] to significant risks of product liability claims . . . . [Intuitive] face[s] financial exposure to product liability claims if the use of [its] products were to cause injury or death. There is also the possibility that defects in the design or manufacture of [Intuitive's] products might necessitate a product recall . . . . Although [Intuitive] maintain[s] product liability insurance, the coverage limits of these policies may not be adequate to cover future claims . . . . A product liability or negligence claim or any product recalls could also harm [Intuitive's reputation] or result in a decline in revenues."

173. Each of the Periodic Filings also warned stockholders that "[Intuitive was] and may become subject to various legal proceedings and claims that arise in or outside [of] the ordinary course of business . . . . The results of these lawsuits and other legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses . . . . Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If [Intuitive] do[es] not prevail . . . [it] may be faced with significant monetary damages . . . that may adversely affect [its] business, financial condition and results of operations, possibly materially."

174. Defendants also continually misrepresented the Company's financial health during the Relevant Period by announcing, and often increasing, revenue guidance, while failing to disclose that Intuitive would face severe legal and regulatory problems in the near future.

175. The Periodic Filings reveal that Defendants, including the members of the Board, were aware of their regulatory obligations. Thus, their repeated failure to comply can only be the result of a willful effort to keep health and safety problems quiet.

I. The Insider Selling Defendants' Illicit Insider Sales

176. During the Relevant Period, the Insider Selling Defendants engaged in stock sales that were suspiciously timed, out-of-line with prior trading practices, and consummated while in the possession of material nonpublic information. Collectively, the Insider Selling Defendants sold over

411,000 shares of Intuitive stock for over $219 million in proceeds in the Relevant Period. As a result of their knowledge of proprietary information about the mismanagement of the Company, and the false and misleading statements and omissions they made or allowed to be made, the Insider Selling Defendants profited from this suspicious trading activity in Intuitive's stock.

177. During the Relevant Period:

(a) Guthart sold 17,000 Intuitive shares for approximately $8.7 million in proceeds;

(b) Smith sold 187,422 Intuitive shares for approximately $100 million in proceeds;

(c) Halvorson sold 4,500 Intuitive shares for approximately $2.5 million in proceeds;

(d) Levy sold 6,750 Intuitive shares for approximately $3.4 million in proceeds;

(e) Loop sold 5,000 Intuitive shares for approximately $2 million in proceeds;

(f) Mohr sold 26,800 Intuitive shares for approximately $15 million in proceeds;

(g) Brogna sold 39,042 Intuitive shares for approximately $18.3 million in proceeds;

(h) Castello sold 26,250 Intuitive shares for approximately $15.1 million in proceeds;

(i) McNamara sold 55,625 Intuitive shares for approximately $31.5 million in proceeds;

(j) Meltzer sold 27,500 Intuitive shares for approximately $15.2 million in proceeds;

(k) Morales sold 4,760 Intuitive shares for approximately $2.3 million in proceeds; and

(l) Rosa sold 11,000 Intuitive shares for approximately $5.7 million in proceeds.

178. Each of the Insider Selling Defendants breached their fiduciary duties by selling shares while knowing of, and causing or allowing Intuitive to withhold, critical information regarding: (i) known defects of the *da Vinci* system, (ii) Intuitive's failure to comply with FDA

adverse event reporting regulations, (iii) Intuitive's failure to report covert corrective actions responding to known *da Vinci* system defects to the FDA, (iv) Intuitive's wrongful off-label marketing of the *da Vinci* system, (v) Intuitive's lack of appropriate internal controls for reporting adverse events and corrective actions to the FDA, (vi) Intuitive's materially false and misleading public misstatements and omissions regarding the *da Vinci* system and FDA regulatory compliance, (vii) Intuitive's possible out-of-pocket exposure in pending, threatened, or contemplated products liability lawsuits due to its scheme to renew its products liability insurance while hiding pending and threatened products liability lawsuits from its insurance carriers, and (viii) the rampant insider trading occurring at the Company. Each of the Defendants who did not sell shares breached their fiduciary duties by failing to prevent these insider sales.

179. Many of these insider sales occurred shortly after the Company's covert recalls in October 2011. These secret corrective actions were in direct violation of FDA reporting requirements, of which responsibility the Insider Selling Defendants were "presumed to be fully aware." In particular, Defendants McNamara, Levy, and Loop sold a collective 9,257 shares on October 21, 2011 for almost $3.75 million. Further, Defendant Smith sold 15,000 shares on October 25, 2011 for almost $6.3 million.

180. Additional insider sales occurred shortly after the Company's undisclosed conversation with the FDA in September 2012 regarding Intuitive's reporting practices. After this meeting, the Insider Selling Defendants knew that Intuitive's era of underreporting injuries and consequent inflated stock price was coming to a rapid end. Between October and early December 2012, Defendants Smith, Guthart, Mohr, Brogna, and McNamara sold over 150,000 shares of Intuitive stock collectively for over $80 million. Significantly, Defendant Smith's sales alone accounted for approximately $70 million.

181. Insider sales also took place in January 2013, after the FDA began its probe into Intuitive, but before such information was made public and while Intuitive stock was trading at near all-time highs. The Insider Trading Defendants knew that the information regarding the FDA probe and reporting violations would promptly become public, which in fact it did, sparking sharp stock price declines a few months later in March and July 2013. Specifically, Defendants Guthart, Mohr,

McNamara, Meltzer, and Halvorson sold over 32,000 shares collectively for over $18 million in January 2013.

182. Notably, some of the Insider Selling Defendants made sales after adopting 10b5-1 plans. Pursuant to SEC Rule 10b5-1(c), a 10b5-1 plan is a safe harbor for an insider who trades shares while aware and in possession of material nonpublic information. A 10b5-1 plan allows an insider to make a binding plan in advance for the timing and amount of his or her stock sales, insulating the insider from insider trading liability.

183. However, a 10b5-1 plan is a defense to insider trading liability only if it is entered into before the insider became aware of the material, nonpublic information and the plan was otherwise established in good faith and not as part of a plan or scheme to evade the prohibition against insider trading. The adoption or modification of a 10b5-1 plan ***while*** in possession of material nonpublic information contravenes the purpose of the safe harbor, and supports a strong inference of illegal trading activity.

184. Thus, although some of the Insider Selling Defendants made sales after adopting 10b5-1 plans, the circumstances surrounding the adoption of those plans are sufficiently suspicious to overcome any exculpatory inferences. The Insider Selling Defendants adopted the 10b5-1 plans after learning about the substantial defects with the *da Vinci* system and the covert corrective actions, in order to take advantage of artificially inflated stock prices that they knew would eventually plummet when the truth regarding the *da Vinci* system's defects – and their violation of FDA reporting obligations – became publicly known.

185. Insider Selling Defendants Guthart, Smith, Mohr, Castello, McNamara, Meltzer, Halvorson, and Levy all adopted 10b5-1 plans in March 2012, and Brogna adopted one in June 2012. Each of these plans was adopted ***after*** Defendants authorized, allowed, and/or knew of the secret corrective actions taken by the Company in October 2011. Thus, the plans were entered into based on the adoptees' knowledge of materially nonpublic information and in the absence of good faith.

186. Smith also ***modified his 10b5-1 plan*** on February 1, 2013 – after the FDA probe began but before it became public – and made trades under the modified plan. Similarly, both Smith

and Halvorson made substantial sales ***outside*** of their 10b5-1 plans. Smith sold ***over 109,000 shares outside of his 10b5-1 plan for almost $60 million in proceeds***.

187. Notably, these insider sales were often executed at the same time that, per the Board's authorization, the Company was buying back hundreds of millions of dollars' worth of its own stock with Company (*i.e.*, shareholders') money, propping up Intuitive's share price even further. Specifically, in February 2011, the Board increased its authorization of a stock repurchase of up to $400 million, and in October 2011 – the same time Defendants' "secret recall" campaign began – the Board increased its authorization for stock repurchases by another $500 million. Later, in March 2013, the Board authorized another $1 billion in stock repurchases.

188. As discussed above, the Compensation Committee Defendants had an independent obligation to prevent the adoption of compensation plans that allowed for rampant insider trading. According to the applicable Charter, the Compensation Committee's purpose "is to, among other things, discharge the Board's responsibilities relating to the compensation of the Company's executives."

[redacted]

[redacted]

191. Defendants' failure to consider, implement, and/or oversee adequate controls to ensure that 10b5-1 plans were only entered into in good faith, were not manipulated or bypassed, and not used to mask impermissible insider trading liability was a breach of their fiduciary duties.

J. Defendants' Breaches Have Caused Harm to the Company

192. Defendants' breaches of fiduciary duty have harmed the Company in at least three ways.

193. ***First***, each of the Insider Selling Defendants has exploited the Company's confidential information for their own gain and therefore may be held liable to the Company.

194. During the Relevant Period the Insider Selling Defendants possessed material, nonpublic information regarding: (i) known defects of the *da Vinci* system; (ii) Intuitive's failure to comply with FDA adverse event reporting regulations; (iii) Intuitive's failure to report covert corrective actions responding to known *da Vinci* system defects to the FDA; (iv) Intuitive's wrongful off-label marketing of the *da Vinci* system; (v) Intuitive's lack of appropriate internal controls for reporting adverse events and corrective actions to the FDA; (vi) Intuitive's materially false and misleading public misstatements and omissions regarding the *da Vinci* system and FDA regulatory compliance; (vii) Intuitive's possible out-of-pocket exposure in pending, threatened, or contemplated products liability lawsuits due to its scheme to renew its products liability insurance while hiding

pending and threatened products liability lawsuits from its insurance carriers; and (viii) the rampant insider trading occurring at the Company.

195. The Insider Selling Defendants also knew that once this information became public, as it inevitably would, the price of the Company's stock would sharply decline (as it in fact did). The Insider Selling Defendants used that inside information improperly by selling Company stock at inflated prices at near all-time highs before the truth emerged. As discussed in above, the Insider Selling Defendants collectively sold more than $219 million in Intuitive stock during the Relevant Period.

196. Each of the Insider Selling Defendants was an officer or director of the Company during the Relevant Period, and therefore each Insider Selling Defendant owed the Company a fiduciary duty not to use for their own account confidential information that they acquired in the course of their fiduciary relationship. Accordingly, each of the Insider Selling Defendants is liable to the Company for the improper profits that they received as a result of their insider trading.

197. ***Second***, Defendants' breaches of fiduciary duty have exposed the Company to avoidable harms including litigation costs and risks, regulatory risk, and reputational harm.

198. Defendants' misconduct has also resulted in at least 95 products liability actions, and hundreds or thousands of additional claims against the Company that have been tolled by agreement, exposing the Company to litigation costs and a significant risk of civil liability. On April 8, 2014, Intuitive announced a pre-tax charge of $67 million against its first quarter 2014 earnings, reflecting its estimate of the anticipated cost of settling legal claims against the Company. The vast majority of these claims were related to alleged complications from surgeries. The Company's estimate of the anticipated litigation costs was based on negotiations with counsel covering approximately ***3,000*** claims presented to the Company beginning in October 2012. More recently, per the Company's Quarterly Report on Form 10-Q for the second fiscal quarter of 2014, filed with the SEC on July 24, 2014, the Company has been forced to take a $77 million pre-tax charge to reflect estimated costs of resolving "a number of product liability claims," explaining that "[t]o date, approximately 4,400 claims have been added to the tolling agreements and/or submitted to the mediation program."

199. This potential exposure is especially concerning given that, as discussed above, the Insurer Plaintiffs are suing to invalidate Intuitive's products liability insurance policies on the grounds that the Defendants caused Intuitive to hide this potential exposure on the Company's insurance applications.

200. Defendants' misconduct, and the attendant litigation and regulatory proceedings, have harmed the Company's reputation and sales, and resulted in increased regulatory scrutiny. As the Company admitted in its 2013 Form 10-K:

> Current product liability claims have resulted in the negative publicity regarding our Company, and these and any other product liability or negligence claims or product recalls also could harm our reputation. In addition, there have been articles published and papers written questioning patient safety and efficacy associated with *da Vinci* surgery, the cost of *da Vinci* surgery relative to other disease management methods, and the adequacy of surgeon training. Negative publicity, whether accurate or inaccurate, concerning our products or our Company could reduce market acceptance of our products and could result in decreased product demand and a decline in revenues.

201. ***Third***, when the improperly concealed information regarding health and safety concerns with the *da Vinci* system became public, it dramatically affected Intuitive's sales and revenues.

202. After Intuitive's regulatory problems first became publicly known in February 2013, the Company's sales and revenues dropped dramatically. Revenues in the second quarter of 2013, while higher than the second quarter of 2012, were still considerably lower than analysts had anticipated, leading to a substantial drop in the Company's stock price. The Company's revenues for Q3 2013 (during which the July 16, 2013 FDA Warning Letter was disclosed) were $79.5 million (almost 14%) lower than in Q2 2013, and $38.8 million (7%) lower than in the Q3 2012. Intuitive sold 101 *da Vinci* systems in that quarter, a 34.8% decline from the previous year. Similarly, revenues in the fourth quarter declined by 5% and new systems sales declined by 21%. Most recently, the Company's revenues for Q1 2014 were $146.7 million lower than they had been in Q1 2013, a 23.9% decline, and new systems sales declined by 47%.

203. Multiple business journalists and market analysts have concluded that concerns regarding the Company's regulatory compliance (or lack thereof) have contributed to its difficulties in selling units. For example:

A. On March 1, 2013, a *Bloomberg* article entitled, "Intuitive Robot Probe Threatens Trend-Setting Surgeries" stated that "[t]he safety of robots made by [Intuitive] is being probed by U.S. regulators, raising questions about the prospects of one of the hottest technologies in health care."

B. On July 19, 2013, days after the disclosure of the July 16, 2013 FDA Warning Letter, Trefis issued an analyst report stating that the Warning Letter was "another blow" to the Company and "***could hinder approval of new products/procedures going forward***" (emphasis added). The Trefis report also stated that, "[t]he warning letter from the FDA will only worsen conditions as it will make it harder for the company to sell the system."

C. Also on July 19, 2013, a Motley Fool research report stated, "***it wasn't the numbers that sent Intuitive stock nuclear on Thursday after the closing bell. The FDA has picked and prodded at the robotic surgical device maker for some time, but regulators' investigations came to a big climax that culminated in a gut-wrenching one-two punch for investors***" (emphasis added). The report also stated that, "the slump in system sales means that the increasing talk regarding safety and legal issues at the company are catching up to Intuitive's financials – and investors. Thursday's warning by the FDA may only exacerbate that trend."

D. On July 20, 2013, a *Bloomberg* article entitled, "Intuitive Surgical Declines on Warning Letter From FDA" stated that Intuitive's "sales trajectory may have hit a wall amid regulatory scrutiny over adverse events during operations using its surgical robots and concerns on whether the $1.5 million devices are cost effective."

E. On October 6, 2013, a Seeking Alpha research report entitled "Wait For The Next Shoe To Drop Before Buying Intuitive Surgical" stated that Intuitive "has had a difficult 2013 and its troubles may continue. Despite theories that this weakness is related to Obamacare implementation concerns or reductions to hospital budgets, ***[Intuitive's] woes are directly and almost exclusively due to the . . . FDA[] warning letter and the related investigation into the efficacy, safety and use of the company's 'da Vinci' surgical robot, which the company disclosed last quarter. Further, despite theories that the company's recent weakness is probably over, it probably is not. What investors must now recognize is that government investigations are***

generally slow and that [Intuitive's] troubles here are bound to continue for the duration of it. [Intuitive] was priced for substantial growth, and though it is still growing, the company's development shall be stunted until the conclusion of FDA scrutiny. Hospitals will refrain from purchasing new da Vinci robots, whether or not they want or can afford them, while this overhanging regulatory concern persists" (emphasis added).

F. On April 9, 2014, a *Motley Fool* research report entitled, "Why Intuitive Surgical Inc. Shares Were Sliced," discussed expectations that *da Vinci* systems revenue was expected to decrease by approximately 59% in the first quarter of 2014 and stated that "I do believe that the overhang from the ongoing investigation into the safety and efficacy of [Intuitive's] da Vinci surgical system by the Food and Drug Administration had something to do with the drop in demand[.]"

204. It makes sense that reports regarding noncompliance with FDA regulations would harm the Company's sales. Customers will naturally consider the trustworthiness of the manufacturer when determining whether to purchase or use a surgical robot. Even aside from immediate concerns regarding the safety of the *da Vinci* system, patients, physicians, and hospital administrators all depend on the integrity of the data that is submitted to the FDA, and will be less likely to use medical devices manufactured by a manufacturer that has been known to evade reporting requirements and regulations. Further, hospital administrators will be less likely to purchase an expensive device that is facing an overhang of regulatory scrutiny. Similarly, Intuitive will find it more difficult to get products approved inside and outside of the United States, as regulators view the Company with greater circumspection. To the extent that Defendants' breaches of fiduciary duty to ensure legal compliance have injured the Company by harming its reputation and sales, the Defendants are liable to the Company for the resulting damages.

DERIVATIVE AND DEMAND ALLEGATIONS

205. Plaintiff brings this action derivatively in the right and for the benefit of Intuitive to redress the breaches of fiduciary duty and other violations of law by Defendants.

206. Plaintiff has owned Intuitive shares continuously during the Relevant Period, and continues to hold Intuitive shares. Plaintiff will adequately and fairly represent the interests of

Intuitive and its shareholders in enforcing and prosecuting its rights, and has retained counsel experienced in prosecuting stockholder derivative litigation.

207. At the time this action was initiated, the Board consisted of the following nine (9) Director Defendants: Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful and useless act, for the reasons discussed below.

A. The Entire Board Faces a Substantial Likelihood of Liability Because Each Director Defendant Was Aware of Regulatory Violations Concerning the *da Vinci* System and the Company's Lack of Effective Internal Controls

208. During the Relevant Period – indeed, since the Company's inception – one product has been responsible for 100% of Intuitive's revenues and profit, the *da Vinci*. As a result, every member of the Board was aware of numerous red flags regarding the problems the Company was experiencing with the *da Vinci* system. Notwithstanding this knowledge, the Board did not cause Intuitive to disclose these problems to the FDA, and did not adopt internal controls sufficient to ensure regulatory compliance.

209. As Intuitive's 2011, 2012, and 2013 10-Ks all make clear, as the manufacturer of a Class II medical device designed to perform surgical procedures, Intuitive has always been subject to "extensive regulation" by the FDA. These FDA regulations include, among other things:

- "[T]he FDA's general prohibition against false or misleading statements in the labeling or promotion of products for unapproved or 'off-label' uses";
- "[S]tringent complaint reporting and Medical Device Reporting regulations, which require[] that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur";
- "[A]dequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest the same"; and

210. "[T]he reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the [Act] that may pose a risk to health."

211. As is spelled out in the Company's 2011, 2012, and 2013 10-Ks (each of which were signed by all nine Director Defendants), the Board recognized that "complying with FDA regulations is a complex process," and that Intuitive's failure to comply "could lead to an enforcement action that may have an adverse effect on [Intuitive's] financial condition and results of operations." Thus, the Director Defendants were plainly aware of their obligations pursuant to FDA regulations.

212. Nevertheless, throughout the Relevant Period, the Board allowed Intuitive's concealment of known defects to persist. Specifically, as described in detail above, each of the Director Defendants knew of the defects and their concealment from the FDA, or should have, because:

a) From January 2010 through December 2011, the Company received hundreds of complaints about the *da Vinci* system, many of which concerned the Tip Covers designed to insulate the device and protect patients from electricity arcing out of the device. In the two year period between January 2010 and December 2011, Intuitive received 134 complaints but filed only 82 MDRs related to Tip Covers.

b) In January 2011, an article published in the *Journal of Urology*, entitled "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury," detailed a study of over 450 robotic procedures conducted from July 2008 to January 2009. A total of 12 accessory tip cover failures were discovered, demonstrating a failure rate of 2.6%, with a patient complication rate of 0.6% (25% of all failures). Each failure was identified by the arcing of the electrical current from the insulated portion of the monopolar scissors or by an intraoperative injury. Similarly, in August 2011, an article published in the *American Journal of Obstetrics & Gynecology*, entitled "Insulation failure in robotic and laparoscopic instrumentation" found that insulation failure (which was described as an "important cause of electrosurgical injury in minimally invasive surgery that results from damage to the coating that insulates the instrument") occurred in "robotic" laparoscopic surgery at a rate of ***approximately 4-1*** when compared to traditional laparoscopic instruments.

c) In October 2011, the Company began taking secretive corrective action regarding the Tip Cover defect and failed to report this action to the FDA as required. On October 10, 2011, in response to complaints concerning arcing through damaged tip covers causing patient injury (ten months after the very issue was addressed in the January 2011 journal article and three months after it was addressed in the August 2011 journal article), Intuitive sent a letter to hospital customers noting that installation of the Tip Covers on the Advanced Energy Instruments often resulted in tears and fractures due to the degree of force required for installation. The letter also noted that such damaged Tip Covers would not properly insulate electrical current, which causes arcing. None of this information was reported to the FDA, as required by regulations the Company cited in its own SEC Filings.

d) In October 2011, the Company began taking secretive corrective action regarding off-label marketing of the *da Vinci* system for thyroidectomies. On

October 13, 2011, Intuitive sent a letter to hospital customers noting that, despite previous suggestions to the contrary, the *da Vinci* system was ***not*** indicated for thyroidectomies. None of this information was reported to the FDA, as required by regulations the Company cited in its own SEC Filings.

e) One week later, on October 17, 2011, the Company, under Defendants' direction, undertook a third secret corrective action. Intuitive sent another letter to hospital customers, concerning proper care for cannulas. The FDA later identified damaged cannulas as "one of the root causes" of arcing. Again, however, nothing was reported to the FDA as required by regulations cited by the Company in its SEC filings.

[redacted]

i) About one year after the corrective measures, in September 2012, the FDA met with executives from Intuitive to address underreporting of and misrepresentations in the Company's MDRs.

j) As a result, the Company, under Defendants' direction, revised its MDR practices to comply (for the first time) with FDA regulations, the result of which was an at least threefold increase in the number of reported injuries and deaths caused by the *da Vinci* system.

[redacted]

[redacted]

l) In January 2013, as a result of its meeting with Intuitive, the FDA initiated a probe to directly survey hospitals that purchased the *da Vinci* system from Intuitive.

m) Despite the Company's acknowledgment to certain customers two years earlier in the Tip Cover Corrective Action Letter that injuries were occurring because of torn Tip Covers, a March 1, 2013 *Bloomberg* article entitled "Intuitive Robot Probe Threatens Trend-Setting Surgeries," demonstrates that the FDA remained in the dark. The article quotes an FDA spokeswoman questioning why MDRs had increased so dramatically, noting "[w]hat the agency is trying to determine is whether a rise seen in incident reports sent to the agency are a 'true reflection of problems' with the robots, or the result of other issues."

n) On March 5, 2013, an article in *Bloomberg* entitled, "Robosurgery Suits Detail Injuries as Death Reports Rise," detailed the story of Kimberly McCalla, who underwent surgery for early-stage cervical cancer using the *da Vinci*, only to pass away from small bowel damage after several emergency procedures related to a lacerated "iliac artery near the original operation."

o) On March 19, 2013, CNBC aired a report entitled, "Robotic Surgery: Growing Sales, but Growing Concerns," in which one patient, Sonya Melton reported that, "she became so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die." Only after slicing Ms. Melton's stomach open did the doctors discover "a perforation in her small intestine." This same report also highlighted another patient, Shawn Todd, whose ureters had been burned.

p) In its Q2 2013 10-Q filed on April 19, 2013, Defendants caused the Company to disclose that it had seen a "substantial increase" in claims from persons who alleged that they had suffered injuries after undergoing *da Vinci* surgery, and that the Company had entered into tolling agreements with plaintiffs' counsel acting on behalf of such claimants.

q) On July 16, 2013, the FDA delivered the July 16, 2013 Warning Letter to Guthart, as CEO of Intuitive, citing the Company for several violations of the Act in connection with its "failure to submit a written report" regarding the secretive October 2011 corrective actions. The Warning letter stated that the FDA found that Intuitive ***knew*** of the arcing problem as early as 2011.

213. Accordingly, based on the particularized facts alleged herein, and all reasonable inferences to be drawn therefrom, each and every member of the Board knew of and facilitated the regulatory violations at issue in this Complaint. The misconduct at the heart of this Action, perpetrated by both management and the Board, constitutes knowingly and consciously presiding over the Company's willful noncompliance with FDA regulations. The Board affirmatively adopted, implemented, and condoned a business strategy based on deliberate noncompliance with mandatory legal requirements aimed at ensuring effective reporting of safety concerns stemming from medical

devices. Failing to comply with mandatory regulations is not a legally protected business decision and such conduct can in no way be considered a valid exercise of business judgment.

214. Moreover, during the Relevant Period, the Board's composition was identical to the current Board, such that each of the current members of the Board (*i.e.*, the persons to whom a demand would be addressed) was aware of and participated in the above legal violations and faces a substantial possibility of liability in connection with Plaintiff's allegations. Accordingly, demand on the Board is excused.

B. Demand Is Futile as to a Majority of the Director Defendants Due to Their Illicit Insider Selling

215. A majority of the members of the Board are also interested and/or face a substantial likelihood of liability in connection with their illicit insider stock sales discussed above. Significantly, because the following members of the Board comprise a majority of the Board, demand is excused on this basis alone:

a. During the Relevant Period, Defendant Guthart illicitly sold shares of Intuitive stock for proceeds of over $8.7 million while in possession of material, adverse, non-public information, during a time in which Intuitive's stock was artificially inflated due to Defendants' false and misleading statements. As such, Defendant Guthart violated the Company's insider trading policy. As a result of these illicit sales, Defendant Guthart received direct financial benefits not shared with Intuitive's shareholders, and is, therefore, directly interested in a demand. Further, Defendant Guthart is interested in a demand because he faces a substantial likelihood of liability for his breaches of fiduciary duties of loyalty and good faith arising from his illicit insider sales;

b. During the Relevant Period, Defendant Smith illicitly sold shares of Intuitive stock for proceeds of over $100 million while in possession of material, adverse, non-public information, during a time in which Intuitive's stock was artificially inflated due to Defendants' false and misleading statements. As such, Defendant Smith likewise violated the Company's insider trading policy. As a result of these illicit sales, Defendant Smith received direct financial benefits not shared with Intuitive's shareholders, and is, therefore, directly interested in a demand. Further, Defendant Smith is interested in a demand because he faces a substantial likelihood of liability for his breaches of fiduciary duties of loyalty and good faith arising from his illicit insider sales;

c. During the Relevant Period, Defendant Halvorson illicitly sold shares of Intuitive stock for proceeds of over $2.5 million while in possession of material, adverse, non-public information, during a time in which Intuitive's stock was artificially inflated due to Defendants' false and misleading statements. As such, Defendant Halvorson likewise violated the Company's insider trading policy. As a result of these illicit sales, Defendant Halvorson received direct financial benefits not shared with Intuitive's shareholders, and is, therefore, directly interested in a demand. Further, Defendant Halvorson is interested in a demand because he faces a

substantial likelihood of liability for his breaches of fiduciary duties of loyalty and good faith arising from his illicit insider sales;

d. During the Relevant Period, Defendant Levy illicitly sold shares of Intuitive stock for proceeds of over $3.4 million while in possession of material, adverse, non-public information, during a time in which Intuitive's stock was artificially inflated due to Defendants' false and misleading statements. As such, Defendant Levy likewise violated the Company's insider trading policy. As a result of these illicit sales, Defendant Levy received direct financial benefits not shared with Intuitive's shareholders, and is, therefore, directly interested in a demand. Further, Defendant Levy is interested in a demand because he faces a substantial likelihood of liability for his breaches of fiduciary duties of loyalty and good faith arising from his illicit insider sales; and

e. During the Relevant Period, Defendant Loop illicitly sold shares of Intuitive stock for proceeds of over $2 million while in possession of material, adverse, non-public information, during a time in which Intuitive's stock was artificially inflated due to Defendants' false and misleading statements. As such, Defendant Loop likewise violated the Company's insider trading policy. As a result of these illicit sales, Defendant Loop received direct financial benefits not shared with Intuitive's shareholders, and is, therefore, directly interested in a demand. Further, Defendant Loop is interested in a demand because he faces a substantial likelihood of liability for his breaches of fiduciary duties of loyalty and good faith arising from his illicit insider sales.

C. Other Reasons Why Demand Is Futile

216. A pre-suit demand on the Board is likewise futile for the following reasons:

a. During the Relevant Period, Defendants Halvorson, Rubash, and Stalk served as members of the Audit Committee. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee were and are responsible for, *inter alia*, reviewing the Company's annual and quarterly financial reports and reviewing the integrity of the Company's internal controls. Defendants Halvorson, Rubash, and Stalk breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted the Company to disseminate false and misleading statements in the Company's SEC filings and other disclosures and caused the above-discussed internal control failures. Therefore, Defendants Halvorson, Rubash, and Stalk each face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;

b. During the Relevant Period, Defendants Halvorson, Johnson, and Levy served as members of the Compensation Committee. Pursuant to the Company's Compensation Committee Charter, the members of the Compensation Committee were and are responsible for, *inter alia*, the Insider Selling Defendants' 10b5-1 plans. Accordingly, Defendants Halvorson, Johnson, and Levy breached their fiduciary duties of due care, loyalty, and good faith because the Compensation Committee, *inter alia*, knew or should have known that the Insider Selling Defendants were selling massive amounts of stock while in possession of material, nonpublic information. Therefore, Defendants Halvorson, Johnson, and Levy each face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;

c. At the time the action was initiated, the principal professional occupation of Defendant Guthart was his employment with Intuitive as its CEO, pursuant to which he has received and continues to receive substantial monetary compensation and other benefits. In addition, according to the Company's Proxy Statement filed with the SEC on March 6, 2013 (the "2013 Proxy"), Defendants have admitted that Defendant Guthart is not independent. Thus, Defendant Guthart lacks independence from demonstrably interested directors, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action. In addition, Defendant Guthart faces a substantial likelihood of liability for his illicit sales of Intuitive stock, as set forth above; and

d. The principal professional occupation of Defendant Smith from 1997 until at least 2013 was his employment with Intuitive as its CEO and later as an executive, pursuant to which he received substantial monetary compensation and other benefits. In addition, according to the 2013 Proxy, Smith is not listed as a non-employee director, and Defendants accordingly admit that Defendant Smith is not independent. Thus, Defendant Smith lacks independence from demonstrably interested directors, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action. In addition, Defendant Smith faces a substantial likelihood of liability for his illicit sales of Intuitive stock, as set forth above.

COUNT I

Breach of Fiduciary Duty Against the Director Defendants

217. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

218. The Director Defendants all owed and owe fiduciary duties to Intuitive and its shareholders. By reason of their fiduciary relationships, the Director Defendants specifically owed and owe Intuitive the highest obligation of good faith and loyalty in the administration of the affairs of the Company, including the oversight of Intuitive's compliance with federal laws and regulations governing medical device safety and reporting.

219. In addition, the Board had specific fiduciary duties as defined by the Company's corporate governance documents, including the Code and the charters of various Board committees, and principles that, had they been discharged in accordance with the Board's obligations, would have necessarily prevented the misconduct during the Relevant Period and the consequent harm to the Company alleged herein.

220. The Director Defendants consciously violated their corporate responsibilities in at least the following ways.

221. As a direct and proximate result of the Director Defendants' conscious failure to perform their fiduciary duties, Intuitive is now a target of dozens of products liability lawsuits, a two lawsuits brought by its insurance carriers seeking to void insurance contracts held by the Company, and increased regulatory scrutiny. Thus, as a result of the Director Defendants' malfeasance, Intuitive has sustained, and will continue to sustain, significant damages, both financially and to its corporate image and goodwill. Such damages include, and will include, the damages awards, settlements, penalties, fines, expenses, increased regulatory scrutiny (including increased difficult in obtaining future FDA approvals), and other liabilities described herein.

222. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

COUNT II

Breach of Fiduciary Duty Against the Officer Defendants

223. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

224. By reason of their positions as fiduciaries to the Company, the Officer Defendants owed duties of good faith, loyalty, candor, and truthful disclosure. The Officer Defendants were well aware of the relevant medical device laws and regulations, and were duty-bound to enforce the Company's compliance with those laws and regulations.

225. Nevertheless, the Officer Defendants consciously violated and breached these duties by causing Intuitive to willfully ignore the mandatory recording and reporting requirements of the Act and FDA regulations for a prolonged period of time. In fact, the Officer Defendants actively concealed Intuitive's failure to comply with regulations, and went so far as to covertly address product defects without notification to the FDA. The Officer Defendants authorized and implemented Intuitive policies and practices that they knew or should have known to be inadequate for monitoring and enforcing compliance with the FDA's mandatory recording and reporting requirements.

226. As a direct and proximate result of the Officer Defendants' breaches of fiduciary duty, Intuitive has sustained, and will continue to sustain, substantial harm. Such damages include,

and will include, the damages awards, settlements, penalties, fines, expenses, increased regulatory scrutiny (including increased difficult in obtaining future FDA approvals), and other liabilities described herein.

227. As a result of the misconduct alleged herein, the Officer Defendants are liable to the Company.

COUNT III

Against All Defendants for Unjust Enrichment

228. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

229. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense and to the detriment of Intuitive.

230. Defendants were unjustly enriched as a result of the compensation they received while breaching their fiduciary duties owed to the Company.

231. Plaintiff, as a stockholder and representative of Intuitive, seeks restitution from Defendants and an order from this Court disgorging all profits, benefits, and other compensation obtained by Defendants from their wrongful conduct and fiduciary breaches.

232. Plaintiff, on behalf of Intuitive, has no adequate remedy at law.

COUNT IV

Breach of Fiduciary Duty and Misappropriation of Information Against the Insider Selling Defendants

233. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

234. At the time the Insider Selling Defendants sold their Intuitive stock, they knew the material, nonpublic information described above, and sold Intuitive stock on the basis of such information.

235. The material, nonpublic information at issue was proprietary information regarding the Company's business and financial condition. It was a proprietary asset belonging to the

Company, which the Insider Selling Defendants used for their own benefit when they sold Intuitive stock.

236. Since the use of the Company's proprietary information for their own gain constitutes a breach of the Insider Selling Defendants' fiduciary duties, the Company is entitled to the imposition of a constructive trust on any profits they obtained thereby.

237. Plaintiff, on behalf of Intuitive, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Determining that this action is a proper derivative action maintainable under law and demand is excused;

B. Declaring that Defendants named herein have breached their fiduciary duties, as alleged herein;

C. Directing that Intuitive and Defendants take all necessary actions to reform and improve Intuitive's corporate governance and internal controls, policies, and procedures to comply with the Company's governance obligations and all applicable laws and regulations, and to protect the Company and its stockholders from a recurrence of the damaging events described herein, including by directing that Intuitive adopt, maintain, execute, and oversee appropriate internal controls, policies, and procedures for ensuring compliance with all FDA reporting obligations;

D. Requiring that Defendants pay to the Company the amounts by which it has been damaged or will be damaged by reason of the conduct complained of herein;

E. Ordering disgorgement by the Insider Selling Defendants to Intuitive of all profits gained and losses avoided contemporaneously with the sale by these Defendants of Intuitive common stock during the Relevant Period;

F. Awarding to Plaintiff costs and disbursements of the action, including reasonable attorneys' fees, accountants' consultants' and experts' fees, and expenses; and

G. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 13, 2014

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Additional Counsel

VERIFICATION

I, Robert Berg, under penalty of perjury, state as follows:

I am the Plaintiff in the above-captioned action. I have read the foregoing Complaint and authorized its filing. Based upon the investigation of my counsel, the allegations in the Complaint are true to the best of my knowledge, information and belief.

DATED: August 11, 2014

Robert Berg

Robert Berg

Mailing Information for a Case 5:14-cv-00515-EJD In re Intuitive Surgical Shareholder Derivative Litigation

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who

therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)